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UNITED STATES PATENT APPLICATION

FOR

USE OF DOCOSAHEXAENOIC ACID AND ARACHIDONIC ACID ENHANCING THE GROWTH OF PRETERM INFANTS

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CROSS-REFERENCE TO RELATED PATENT APPLICATIONS

The present application is a Divisional of United States Patent Application Serial No. 09/381,484, filed February 19, 2002, which is a Continued Prosecution Application of United States Non-provisional Patent Application Serial No. 09/381,484, filed September 21, 1999 under 35 U.S.C. § 371, which is a National Phase Application of International Application No. PCT/US98/10566, filed March 20, 1998, which designated the United States and claims the benefit of United States Provisional Application Serial No. 60/042,366, filed March 27, 1997, and claims the priority benefit of each of these applications, each of which is incorporated herein by reference in its entirety, and is related to a commonly assigned and copending application having the title "Use of Docosahexaenoic Acid and Arachidonic Acid Enhancing The Growth of Preterm Infants", which was filed on the same date as the present application.

BACKGROUND OF THE INVENTION

(1) Field of the Invention:

The present invention concerns enhancing the growth of preterm infants involving administration of infant formula containing a combination of docosahexaenoic and arachidonic acid.

(2) Description of the Related Art:

The long chain polyunsaturated fatty acids (LC PUFA) have been shown to be important in infant development. Particularly, arachidonic acid (ARA) and docosahexaenoic acid (DHA) are LC PUFA that are of special interest in infant nutrition because they are found in high concentrations in the brain (Sastry PS, Lipids of nervous tissue: composition and metabolism. Progress Lipid Res 1985;24:69-176) and the retina (Fliesler SJ and Anderson RE. Chemistry and metabolism of lipids in the vertebrate retina. Progress Lipid Res 1983;22:79-131). ARA

(20:4n-6) and DHA (22:6n-3) are derived from the parent essential fatty acids linoleic acid (18:2n-6) and α-linolenic acid (18:3n-3) through alternate desaturation and elongation and accumulate rapidly in fetal neural tissue during the last months of gestation and the first months of postnatal life (Makrides M, Neuman MA, Byard RW, Simmer K, Gibson RA. Fatty composition of the brain, retina and erythrocytes in breast- and formula-fed infants. Am J Clin Nutr 1994;60:189-94).

Unlike term infants, preterm infants do not fully benefit from the maternal and placental LC PUFA supply during the last trimester of pregnancy. Even though preterm infants are capable of synthesizing both DHA and ARA from their 18 carbon precursors (Carnielli VP, Wattimena DJL, Luijendijk IHT, Boerlage A, Degenhart HJ, Sauer PJJ. The very low birth weight premature infant is capable of synthesizing arachidonic and docosahexaenoic acids from linoleic and linolenic acids. Pediat Res 1996;40:169-174), it remains unclear whether the rate of synthesis is adequate to meet the optimal needs for central nervous system accretion in the absence of a dietary supply of these fatty acids. Preterm infants are dependent on their own dietary supply of linoleic and α-linolenic acids through either human milk, which also contains small but significant amounts of ARA and DHA or through commercially available artificial formulas, none of which in the United States contain ARA end DHA.

It has been demonstrated in recent studies (Hoffman DR and Uauy R. Essentiality of dietary ω-3 fatty acids for premature infants: Plasma and red blood cell fatty acid composition. Lipids 1992;27:886-95) that the fatty acid composition of red blood cell membrane lipids in infants receiving formulas supplemented with DHA (0.35% of total fatty acids) was similar to human milk-fed infants. In the same study, Birch (Birch DG, Birch EE, Hoffman DR Uauy RD. Retinal development in very-low-birth-weight infants fed diets differing in Omega-3 fatty acids. Investigation Ophthalmology Visual Science 1992;33:2365-76) found that retinal function improved with the provision of a dietary supply of DHA in very low birth weight infants.

The first year growth of preterm infants fed standard formula compared to marine oil LC PUFA supplemented formula was studied by Carlson et al. (Carlson SE, Cooke, RJ, Werkman SH, Tolley EA. First year growth of preterm infants fed standard compared to marine oil n-3 supplemented formula Lipids 1992:27:901-907). The experimental formulas provided 0.2% of total fatty acids as DHA and also provided 0.3% as EPA (20:5n-3). This EPA concentration is higher than found in human milk while the DHA level is similar to human milk. Beginning at 40 weeks from conception, marine oil supplemented infants compared to controls had significantly lower weight, length, and head circumference. From this study, Carlson (Carlson SE, Werkman SH, Peeles JM, Cooke RJ, Tolley EA. Arachidonic acid status correlates with first year growth in preterm infants. Proc Natl Acad Sci USA 1993;90:1073-77) hypothesized that dietary ARA could improve first year growth of preterm infants, in the context of restoring growth to the level of control formula containing no LC PUFA.

In another study (Montalto, FB, et al., Pediatric Research, Vol 39, page 316A, abstract no. 1878) it was shown that male infants fed marine oil supplemented formula (containing DHA but essentially no ARA) had, by 4 to 6 months, lower head circumference, length, weight and fat free mass than standard formula fed infants. A third study also showed decreased weight at 9 and 12 months corrected age in preterm infants fed marine oil supplemented formula (with LC PUFA) to 2 months corrected age compared with control formula containing no LC PUFA (Carlson SE, et al., Am. J. Clin. Nutr., 63 pp 687-97, 1996).

The prior art has demonstrated that infants with altered tissue LC PUFA levels, resulting from a lack of LC PUFA in their diets, may be at risk for neurological problems, may also have reduced scores on cognitive tests, and may have lower retinal development than human milk-fed infants. Worldwide regulatory organizations such as the WHO/FAO Expert Committee on Fats and Oils in Human Nutrition have recommended that LC PUFA be included in preterm infant formula.

These recommendations have been made despite the negative effects observed of DHA supplements on growth. There has been no demonstration in the literature that ARA and DHA, particularly when added to infant formula, enhances the growth of infants above that demonstrated by control formulas not containing ARA and DHA.

SUMMARY OF THE INVENTION

It has unexpectedly been discovered that preterm infants receiving infant formula supplemented with both DHA and ARA demonstrate enhanced growth. The present invention is directed to enhancing the growth of preterm infants comprising administering to said infants a growth enhancing amount of DHA and ARA.

DETAILED DESCRIPTION OF THE INVENTION

As reported in a review of preterm infant growth by Carlson, SE, (The Jrnl of Pediatrics, vol 125, pp 533-8, 1994) "After adjusting for postconceptional age, preterm infants show a decline (rather than a catch-up) in the normalized weight from approximately 2 to 4 months past expected term."

Several prior art studies have documented the value of administering DHA to infants. However, when DHA, either as the primary LC PUFA or combined with EPA, is administered to preterm infants, said infants suffer from decreased growth. It has been suggested that ARA may be beneficial to growth; however, heretofore the growth effects of administering both DHA and ARA to preterm infants have been unknown. It has been surprisingly discovered that administering the combination of ARA and DHA results in enhanced growth of infants relative to infants fed DHA alone. It has also been discovered that preterm infants administered an infant formula containing ARA and DHA exhibit enhanced growth relative to preterm infants fed control formula without DHA and ARA, such as those formulas currently used in modem nurseries. It has further been discovered that practice of the method of the invention results in growth of preterm infants catching up in an unexpected short time to a reference group of normal term breast fed infants.

The time to achieve growth similar or equivalent to normal term breast fed infants by practice of the method of the invention is less than 9 months corrected age; preferably less than 6 months corrected age, more preferably less than 4 months corrected age, even more preferably less than 2 months corrected age, and most preferably no greater than term corrected age.

The method of the invention requires a combination of DHA and ARA. The weight ratio weight of ARA:DHA can be about 1:2 to about 5:1, preferably about 1:1 to about 3:1, and more preferably about 2:1.

In the method of the invention the combination of DHA and ARA is preferably administered as part of an infant formula. The infant formula for use in the present invention is preferably nutritionally complete and typically contains suitable types and amounts of lipid, carbohydrate, protein, vitamins and minerals. The amount of lipid or fat typically can vary from about 3 to about 7 g/100 kcal. The amount of protein typically can vary from about 1 to about 5 g/100 kcal. The amount of carbohydrate typically can vary from about 8 to about 12 g/100 kcal. Protein sources can be any used in the art, e.g., nonfat milk, whey protein, casein, soy protein, hydrolyzed protein, amino acids, and the like. Carbohydrate sources can be any used in the art, e.g., lactose, glucose, corn syrup solids, maltodextrins, sucrose, starch, rice syrup solids, and the like. Lipid sources can be any used in the art, e.g., vegetable oils such as palm oil, soybean oil, palmolein, coconut oil, medium chain triglyceride oil, high oleic sunflower oil, high oleic safflower oil, and the like. Conveniently, commercially available infant formula can be used. For example, Enfamil®, Enfamil® Premature Formula, Enfamil® with Iron, Lactofree®, Nutramigen®, Pregestimil®, ProSobee® (available from Mead Johnson & Company, Evansville, Indiana, U.S.A.), Similac®, Isomil®, Alimentum®, Neocare®, and Similac® Special Care (available from Ross Laboratories, Columbus, Ohio, U.S.A.), may be supplemented with suitable levels of ARA and DHA at the proper ratios and used in practice of the method of the invention.

The form of administration of the DHA and ARA in the method of the invention is not critical, as long as a growth enhancing amount is administered. Most conveniently, the DHA and ARA are supplemented into infant formula which is then fed to the infants. Alternatively, the DHA and ARA can be administered as a supplement not integral to the formula feeding, for example, as oil drops, sachets, in combination with other nutrient supplements such as vitamins, and the like.

The growth enhancing amount of DHA is typically about 2.5 mg/kg of body weight/day to about 60 mg/kg of body weight/day, preferably about 6 mg/kg of body weight/day to about 40 mg/kg of body weight/day, more preferably about 12 mg/kg body weight/day to about 30 mg/kg body weight/day, and even more preferably about 18 mg/kg of body weight/day to about 24 mg/kg of body weight/day.

The growth enhancing amount of ARA is typically about 5 mg/kg of body weight/day to about 120 mg/kg of body weight/day, preferably about 12 mg/kg of body weight/day to about 80 mg/kg of body weight/day, more preferably about 24 mg/kg body weight/day to about 60 mg/kg body weight/day, and even more preferably about 36 mg/kg of body weight/day to about 48 mg/kg body weight/day.

The amount of DHA in infant formulas for use in the present invention typically varies from about 2 mg/100 kilocalories (kcal) to about 50 mg/100 kcal, preferably about 5 mg/100 kcal to about 33 mg/100 kcal, more preferably about 10 mg/100 kcal to about 25 mg/100 kcal, and even more preferably about 15 mg/100 kcal to about 20 mg/100 kcal.

The amount of ARA in infant formula for use in the present invention typically varies from about 4 mg/100 kcal to about 100 mg/100 kcal, preferably about 10 mg/100 kcal to about 67 mg/100 kcal, more preferably about 20 mg/100 kcal to about 50 mg/100 kcal, and even more preferably about 30 mg/100 kcal to about 40 mg/100 kcal.

The infant formula supplemented with oils containing DHA and ARA for use in the present invention can be made using standard techniques known in the art. For example, replacing an equivalent amount of an oil

normally present, e. g., high oleic sunflower oil.

The source of the ARA and DHA can be any source known in the art such as fish oil, single cell oil, egg yolk lipid, brain lipid, and the like. The DHA and ARA can be in natural form, provided that the remainder of the LC PUFA source does not result in any substantial deleterious effect on the infant. Alternatively, the DHA and ARA can be used in refined form. It is preferred that the LC PUFA used in the invention contain little or no EPA. For example, it is preferred that the infant formulas used herein contain less than about 20 mg/100 kcal EPA; preferably less than about 10 mg/100 kcal EPA; more preferably less than about 5 mg/100 kcal EPA; and most preferably substantially no EPA.

Preferred sources of DHA and ARA are single cell oils as taught in U.S. patent nos. 5,374,657, 5,550,156, and 5,397,591, the disclosures of which are incorporated herein by reference in their entirety.

The following examples are to illustrate the invention but should not be interpreted as a limitation thereon.

EXAMPLES

I

CLINICAL STUDY DESIGN

1. INTRODUCTION

This study is a double-blind, randomized, controlled parallel design, prospective trial of premature infant formulas containing microalgae and fungi-derived oils which contain a part of their constituents arachidonic acid and docosahexaenoic acid. Formula feeding subjects will be randomized into one of 3 feeding groups:

- premature formula plus DHA (about 0.13% of energy) and ARA (about 0.26% of energy)
- premature formula plus DHA (about 0.13% of energy)
- premature formula WITHOUT DHA and ARA

The products have the same nutrient composition (see Appendix A) and differ only in the level of DHA and ARA. The products will be blinded. The present order of formula has no relationship to randomization.

Normal, term, breast fed infants will be enrolled to provide a normal visual acuity reference.

Fifty evaluable subjects will be completed in each group. Premature infants will remain on study formulas after reaching 90 kcal/kg/d for a minimum of 28 days or until hospital discharge whichever is longer. After 28 days or discharge, whichever is longer, all premature infants will receive Enfamil or Enfalac with Iron. If medically indicated, ProSobee, Lactofree, Alactamil, Nutramigen, or Pregestimil may be used in place of Enfamil or Enfalac with Iron. Term infants will receive at least 85% of their nutrition from breast milk. Primary measures of effectiveness will include visual acuity and red blood cell membrane fatty acid profiles (i.e. DHA and ARA levels). The measure of safety will be growth and adverse experience reports.

2. SUBJECTS

2.1 SOURCE AND CHARACTERIZATION OF STUDY GROUP

Acceptable preterm subjects will be relatively healthy premature infants taking preterm formula. Anticipated hospitalization should be sufficient to allow for 28 days of enteral intake ≥ 90 kcal/kg/d and ≥ 85% study formula intake. All races and both sexes will be eligible for the study.

2.2. INCLUSION CRITERIA

Preterm infants:

- Birth weight ≥ 900 g
- Formula feeding at time of study enrollment
- Anticipate enteral intake of ≥90 kcal/kg/day for ≥ 28 days before discharge home
- Informed consent obtained

Term Infants:

- 38 to 42 weeks gestation
- Committed to breast feeding
- Informed Consent obtained

2.3 EXCLUSION CRITERIA

Preterm infants:

- ≥ 1500 g at birth

Preterm and Term Infants:

- History of underlying disease or congenital malformation which in the opinion of the investigator is likely to interfere with the evaluation of the subject
- More than 24 days between birth and full oral feeds (≥ 90 kcal/kg/d)
- Small (<l0th percentile) for gestational age at birth (SGA)
- Necrotizing enterocolitis as diagnosed by the physician
- Other gastrointestinal disease

- Impaired visual or ocular status at birth

2.4 CONCOMITANT MEDICATIONS, HOSPITALIZATIONS, ILLNESSES

- No medication which may affect FPL response may be used within 3 days of measurement.
- No evidence of viral of bacterial infection during FPL testing.
- No medications known to affect lipid metabolism (e.g., heparin at therapeutic levels)

3. STUDY PRODUCT INFORMATION

3.1 FORMULATIONS

Nutrient composition is included as Appendix A.

4. STUDY PROCEDURES

4.2.1 ENROLLMENT

Enrollment will take place over a 6 month period. Ideally, sufficient subjects will be enrolled so that 10 subjects in each group complete the study at each site for the multi-center trial. A total of 50 infants per formula group will complete this trial.

4.2.2 SCHEDULE OF EVENTS (SEE FLOW CHART, SECTION 8.4)

4.2.2.1 RECRUITMENT

Mothers of eligible, healthy, preterm formula fed infants and term, breastfed infants will be contacted, the study explained to them, and if they are agreeable, written informed consent obtained.

Term infants may be enrolled anytime from birth until or during the 48 week visit.

4.2.2.2 RANDOMIZATION

Recruited formula fed subjects will be randomized into study groups. Randomization can occur anytime after enteral feeds reach 50 kcal/kg/day until commencement of full enteral feeds (i.e., ≥90 kcal/kg/day).

4.2.2.3 FEEDING

All premature infants will receive their assigned study formula after informed consent has been granted and enteral feeds are at least 50 kcal/kg/day. The infant will remain on study formula 28 days after reaching 90 kcal/kg/d or until hospital discharge, whichever is longer. Oral feeding amount, strength and rate will advance as appropriate for the clinical management of the infant.

All parents will be instructed not to feed solid foods during the study. The parents will be instructed that the study formula or breast milk is to serve as the sole source of food from enrollment to study end.

4.2.2.4 BASELINE DATA COLLECTION

The following data will be collected by the Investigator at the time of enrollment and randomization on the case report forms:

- Informed consent of parent obtained.
- Post conceptual age.
- That the subject is a premature infant, with Birth weight ≥900 gm and ≥1500 gm or a normal term infant between 38 and 42 weeks gestational age.
- That the preterm subject is receiving infant formula or term infant is committed to breast feeding.
- Anticipated preterm infant enteral intake of ≥90 kcal/kg/day for ≥28 days prior to discharge home.
- That the subject has no history of underlying disease, inborn error of metabolism, or congenital malformation which in the opinion of the Investigator is likely to interfere with the evaluation of the study formulas.
- That the subject is not small (<l0th percentile) for gestational age at birth.
- That the subject does not have necrotizing enterocolitis as diagnosed by a physician.

- That the subject does not have a gastrointestinal disease.
- No more than 24 days between birth and full enteral feeds (i.e., ≥90 kcal/kg/day).
- That the subject did not have impaired visual or ocular status at birth.
- Birth date, sex, race.
- Birth weight, length and head circumference

4.2.2.5 INVESTIGATOR PERIODIC DATA COLLECTION

"During hospitalization, preterm subjects will have their weight recorded daily while they are receiving study formula. Length and head circumference will be recorded weekly, along with an additional weight measurement. For a given subject, the same scale should be used for the weekly weight measurement."

"Weight, length, and head circumference will also be recorded at the 40, 48, and 57 week post conceptual age visit (preterm) and 56 and 119 days of age visit (term)."

4.2.2.6 BLOOD DRAW

When preterm infant enrolls in the study and again at termination of study formula (i.e., hospital discharge or 28 days after reaching 90 kcal/kg/d of study product), the Investigator will ascertain that the infant is essentially solely formula fed. If this criteria is met, 1.2 ml/blood will be drawn for blood lipids. The sample will be processed as described in Appendix B.

An attempt will also be made to draw a similar blood sample at the 48 weeks PCA visit when visual acuity is measured in both term and preterm infants.

4.2.2.7 VISUAL ACUITY BY FORCED CHOICE PREFERENTIAL LOOKING (FPL) AT 48 AND 57 WEEKS ± 4 DAYS POST-CONCEPTUAL AGE

When the infant is 48 and 57 weeks ± 4 days post-conceptual age, trained persons at each study site will follow the Teller Acuity Card Procedure for the measurement of visual acuity of all study subjects. It is essential that only persons who are trained in the FPL procedure for determining visual acuity do the testing. If necessary, training of responsible persons and documentation of completion of successful training will be done at Children's Hospital Medical Center Ophthalmology Department in Seattle, Washington, according to the procedure attached as Appendix C.

If the infant cannot complete the procedure at 48 or 57 weeks ± 4 days postconceptual age (i.e., too fussy, too sleepy, too inattentive) the test should be repeated within 7 days.

4.2.2.8 INTERIM EVALUATION

At preterm infant hospital discharge or 28 days after reaching 90 kcal/kg/d of study formula feeding, whichever is longer, the Investigator will fill out an "Interim Evaluation" form. After reviewing the subject's records and discussion with the parents and staff, the Investigator will indicate:

- Whether or not the subject completed at least 28 days of study formula intake ≥ 90 kcal/kg/d and both blood samples obtained
- If the study was not completed, and reason
- Whether or not the subject received steroids (glucorticoids)
- Investigator's evaluation of the study formula

The first and last dates study material was taken will be recorded.

4.2.2.9 FINAL EVALUATION

At the final study visit (57 weeks postconceptual age) or earlier if the subject drops out, the Investigator will fill out a "Final Evaluation" Case Report Form. After reviewing the subject's records and discussion with the parents, the Investigator will indicate whether the

subject:

(1) Completed feeding regiment and all study parameters (i.e., anthropometrics and visual acuity measured).

(2) Did not complete feeding regimen.

(3) Not completed and reason.

4.3 CLINICAL OBSERVATIONS

4.3.1 PHYSICAL EXAMINATIONS

Subjects will have weight, length and head circumferences recorded at birth, weekly while hospitalized, then at 40, 48, and 57 weeks ± 4 days postconceptual age.

Body weight will be measured using an electronic balance or a double beam balance accurate to 10 g or ½ oz with non-detachable weights. During hospitalization, if more than one such balance is employed in the practice, either one balance should be designated the study balance and all study weights will be carried out on that balance for a particular subject, or the balances will be checked and certified to register the same weight throughout the range of weights expected. Outpatient weights will be obtained on a calibrated office scale.

Documentation indicating balance calibration of the outpatient balance carried out within 12 months of study initiation will be supplied to the Sponsor.

Length will be measured with the infant in recumbent position with the help of two examiners and a suitable measuring apparatus. One person holds the subject's head in contact with a fixed vertical headboard and a second person holds the subject's feet, toes pointing directly upward and, also applying gentle traction. The baby is measured from the headboard to the soles of the feet with a non-stretching tape measure.

Head circumference will be measured, employing a flexible, non-stretchable cloth or vinyl tape.

4.3.2 VISUAL ACUITY BY FORCED CHOICE PREFERENTIAL LOOKING (FPL)

Visual acuity will be determined at 48 and 57 weeks ± 4 days postconceptual age according to procedures outlined in Appendix C.

4.3.3 LABORATORY TESTS

Blood will be drawn from preterm infants by heel prick or venipuncture when study formula is begun and terminated. An attempt will be made to draw blood at 48 weeks ± 4 days PCA from both term and preterm infants. Procedures for handling the blood are described in Appendix B.

4.4 FLOW CHART

EVENT	PRETERM						TERM		
	Birth	Enteral Intake >50 kcal/kg/d	Termination of Study Formula †	Visit 1 40 wks ± 4d PCA	Visit 2 48 wks ± 4d PCA	Visit 3 57 wks ± 4d PCA	Visit 1 40 wks ± 4d PCA	Visit 2 48 wks ± 4d PCA	Visit 3 57 wks ± 4d PCA
Randomization		✓							
Study Formula		✓							
Enfamil w/iron			✓	✓	✓	✓			
Human Milk							✓	✓	✓
	Physical						Physical		
Weight	✓	✓*	✓	✓	✓	✓	✓	✓	✓
Length	✓	✓*	✓	✓	✓	✓	✓	✓	✓
Head Circumference	✓	✓*	✓	✓	✓	✓	✓	✓	✓
Blood Draw		✓	✓		✓			✓	
Visual Acuity Test					✓	✓		✓	✓
~~Parental Concerns~~ ILLNESSES				✓	✓	✓		✓	✓
Interim Assessment			✓						
Final Assessment	(when the subject discontinues or completes)						(when the subject discontinues or completes)		

Medical problems related to or affecting formula consumption will be recorded when they occur.
*recorded daily and weekly during hospitalization
†At hospital discharge or 28 days of study formula intake (after reaching 90 kcal/kg/d), whichever is later

5. CRITERIA FOR RESPONSE

Criteria for response will depend upon the following:

- Visual Acuity better than the control formula.
- Visual Acuity comparable to breastfed term infant.
- Red Blood Cell phosphatidyl ethanolamine DHA and ARA weight % greater than formula control group.
- Growth as measured by weight achieved at 48 and 57 weeks postconceptual age comparable to formula control group.

6. STATISTICS

6.1 RANDOMIZATION

If the subject meets the inclusion and exclusion criteria, randomization to one of three formula groups will take place. The randomization schedule will be provided by Mead Johnson Research Center. A separate randomization schedule will be provided for males and females.

6.2 SAMPLE SIZE

The primary parameter of interest is visual acuity as measured by the Forced Choice Preferential Looking (FPL). The minimal clinically relevant difference was determined to be 0.5 octave. A consultant in the field of visual acuity estimated the standard deviation to be 0.5 octave. This value was increased to .7 octave in case more variability was experienced in this study. Thirty-two subjects per group are needed to attain 80% power when testing at an alpha level of 0.05.

A sample size estimate of 50 per group was determined to achieve $\alpha + 0.05$, $\beta + 0.20$, for weight of infants receiving study oil being greater than 400 gm below control at 48 weeks postconceptual age or 500 g below control at 57 weeks postconceptual age with a standard deviation of 800 g. It was therefore determined that 50 subjects per group will be used in the study.

6.3 ANALYTICAL PLAN

Visual acuity data will be recorded in cycles per cm. These

values will be converted to cycles per degree using the following formula:

$$\text{cycles/degree} = \frac{38 \times \text{cycles/cm}}{55}$$

A log transformation will be applied to the data prior to analysis. Analysis of variance techniques will be used to assess feeding regimen group differences in visual acuity. If the overall F test for feeding regimen is significant at an alpha level of 0.05, pairwise comparisons will be made at an alpha level of 0.05. If no significant differences are detected, then a post-study power analysis will be performed to demonstrate that the study had adequate power to detect the minimal clinically relevant difference.

Analysis of variance will be used to assess feeding regimen differences in phosphatidyl choline DHA and ARA levels and in phosphatidyl ethanolamine DHA and ARA levels at each time point. If the overall F test is significant at an alpha level of 0.05, then pairwise comparisons will be made at an alpha level of 0.05.

Analysis of variance will be used to assess feeding regiment differences in weight at 48 and 57 weeks postconceptual age. The statistical model will include terms for feeding regimen, study center, sex and all two-way interactions. Non-significant interactions will be removed from the final statistical model. Two one-sided tests will be performed comparing each experimental formula (EC) with the control formula (CF). The hypothesis to be tested is as follows:

$$H_0 = \text{Weight (CF)} \leq \text{Weight (EF)}.$$

The alternative hypothesis is as follows:

$$H_1 = \text{Weight (CF)} > \text{Weight (EF)}.$$

If H_0 is rejected and the mean weight of the control formula exceeds that of the experimental formula by more than 400 mg at 48 weeks postconceptual age or by 500 g at 57 weeks postconceptual age then the conclusion is that the experimental formula does not exceed that of the experimental formula by more than 400 g at 48 weeks postconceptual age or by 500 mg at 57 weeks postconceptual age then

the conclusion is that the experimental formula does provide adequate growth. If H_0 is not rejected then a post-study power analysis will be performed to demonstrate that the study had adequate power to detect the above mentioned clinically relevant differences. If adequate power is achieved then the conclusion is that the experimental formula does provide adequate growth.

Fisher's exact test will be used to compare the proportion of subjects in each group with illness/symptoms of concern during the study. The analysis will be performed for each type of illness/symptom reported, with classification of investigator terms into similar terminology made as necessary.

APPENDIX A

NUTRIENT COMPOSITION OF FORMULAS

All study formulas are 24 kcal/fl oz and are identical in composition to marketed Enfamil Premature Formula except for the study oils employed. These oils are described in the protocol.

NUTRIENT	STUDY FORMULAS AMOUNT/100 kcal	ENFAMIL WITH Fe
Protein g	3	2.2
Fat, g	5.1	5.6
Carbohydrate, g	11.1	10.3
Vitamin A IU	1250	310
Vitamin D IU	270	63
Vitamin E IU	6.3	.2
Vitamin K mcg	8	8
Thiamine, mcg	200	78
Riboflavin, mcg	300	150
Vitamin B_6, mcg	150	63
Vitamin B_{12}, mcg	0.25	0.23
Niacin, mcg	4000	1250
Folic Acid, mcg	35	15.6
Pantothenate, mcg	1200	470
Biotin, mcg	4	2.3
Vitamin C, mg	20	8.1
Choline, mg	12	15.6
Inositol, mg	17	4.7
Calcium, mg	165	78
Phosphorus, mg	83	53
Magnesium, mg	6.3	7.8
Iron, mg	1.8	0.5
Zinc, mg	1.5	0.78
Manganese, mcg	6.3	15.6

NUTRIENT	STUDY FORMULAS AMOUNT/100 kcal	ENFAMIL WITH Fe
Copper, mcg	125	94
Iodine, mcg	25	6
Sodium mg (mEq)	39 (1.7)	27 (1.17)
Potassium mg(Meq)	103 (2.6)	108 (2.8)
Chloride mg (Meq)	85 (2.4)	63 (1.77)

II

FINAL STUDY REPORT

Study Design:

This double-blind, parallel-group study (project 3338) was carried out in 16 neonatal centers (study numbers 9698-9709, 9712, 9723, 9743, and 9746) in North America. Three premature infant feedings were compared. Each had the same composition except for the incorporation of fungal and/or micro algal oils up to about 3% of the fat blend to provide the experimental levels of docosahexaenoic acid (DHA) and arachidonic acid (ARA). The control formula (C, Enfamil® Premature Formula) contained no DHA or ARA, the DHA formula (D) contained about 0.15% of energy as DHA (0.34% of fat), and the DHA+ARA formula (DA) contained about 0.14% of energy as DHA (0.33% of fat) and 0.27% of energy as ARA (0.60% of fat). The formulas were fed to 284 randomized infants weighing 846 to 1560 grams at birth for at least 28 days. Upon completion of study formula intake, they were given routine infant formula and followed through 4 months gestationally corrected age. A group of 90 exclusively human milk fed term infants were enrolled and followed to 4 months of age as a reference group (H).

Study Objective and Statistical Analysis:

The primary objective of this study was to establish the safety of feeding D or DA to preterm infants during their initial hospitalization as measured 1) by growth, acceptance and tolerance while consuming the

formula for at least 1 month and 2) by close monitoring and observation for a 4 to 5 month follow-up period (4-5 times the treatment period) while consuming unsupplemented routine term infant formula. The primary growth parameter selected was weight with evaluation of the proposition that weight on test formula was greater than or equal to weight on control formula. The one sided statistical test for an adverse effect on growth maximized the power to detect a difference should one be present. A two-sided test was used for all other parameters. A p-value of less than 0.05 was used to establish significance.

Secondary objectives of the study were 1) to evaluate the impact of fatty acid levels in erythrocyte phospholipids at the end of study feeding and 2) to determine if any effect on mean visual acuity greater than half an octave could be demonstrated at 2 and 4 months corrected age.

Results:

Six infants were just outside the weight parameters and five infants just older than the less than 24 days chronological age parameter for enrollment in the study. In each case, judgement by the clinical or medical monitor was made to include them in the study prior to enrollment based on their homogeneity with other study infants in all other particulars, e.g., state of health, type of medical complications, and weight for gestational age. All these infants were included in the analysis of the study results.

The formula groups were comparable at enrollment (See table 1). Post-conceptual age, weight, length, and head circumference at enrollment did not differ among the groups.

All groups experienced comparable final study status (See table 2). Drop outs did not differ among the formula fed groups during hospitalization. There also were no differences in drop outs among the four groups at study completion.

Both formulas D and DA provide adequate growth when compared to formula C (See table 3, figure 1, and Appendix 1). Weight gain during hospitalization was no less on D or DA than on C, 33.3, 34.7, and 30.7 g/day, respectively. Furthermore, no less weight was achieved on D or DA

than on C at 40, 48, and 57 weeks post-conceptual age (See table 4, figure 2, and Appendix 1); statistical power was greater than 0.89 to detect a clinically relevant decrease.

Post-hoc analysis reveals that infants on DA grew faster than infants receiving C and D (See table 5 and figure 1). This enhanced growth provided faster "premature infant catch-up" compared to C and D. Weight achieved by the DA group (3198 g) was higher than C (3075 g) and D (3051 g) at 40 weeks post-conceptual age but had not fully caught up to the term birth weight (3438 g) of group H (See table 4 and figure 2). This catch up trend continued through 48 to 57 weeks by which time the mean weight of group DA did not differ from group H while groups C and D remained significantly lower.

Length was not different among the formula groups either during hospitalization or the follow-up period, although the ordered sequence of mean lengths was the same as for the weights (See table 7 and figure 3). This is likely at least partially due to length being a less sensitive parameter of growth than weight. For the same reason, the mean lengths of group H infants were higher than that of all the premature infant groups at 40, 48 and 57 weeks post-conceptual age indicating slower catch up in this parameter.

Head circumference is the least sensitive parameter of growth and was not different among any of the four groups at any time measured except at 40 weeks postconceptual age (See table 8 and figure 4). At this time, as expected, the birth head circumference of group H was smaller than the formula fed premature infants possibly due to molding of labor and to insufficient time for adjustment to the extrauterine environment.

Visual acuity has reportedly been enhanced in studies where DHA supplemented formulas were fed to premature infants both in the hospital and continuing after discharge. In this study, visual acuity was measured about 3 months and then about 5 months after stopping study formula to determine whether a residual beneficial effect of at least half an octave might be observed. Although no difference in visual acuity was found

among the formula groups at these times (See table 8 and figure 5), the acuity card method used, the length of study formula feeding, and/or the length of time not on study formula at the time of measurement may have precluded its detection. However, at 57 weeks post-conceptual age, the breast fed term infant group did have statistically higher visual acuity scores than the test formula groups. But even these differences were at most only 0.33 octave and were clinically insignificant (See figure 6). It is important to note that the breast fed infants continued to receive DHA and ARA during the 3-5 month follow-up period while the formula fed groups did not. Thus, this minor difference in performance was not unexpected based on previous study findings and on developmental differences between term and preterm infants even at the same gestational age.

Individual fatty acid levels were determined in the phosphatidylcholine and phosphatidylethanolamine fractions of red blood cells before formula feeding, at the conclusion of test formula feeding, and at 48 weeks post-conceptual age (See tables 9 and 10). The premature infant groups were comparable at the beginning of test formula feeding. At the conclusion of test formula feeding, individual fatty acid levels varied among the groups. DHA and ARA were statistically significantly higher in the respectively supplemented groups. Other fatty acid levels reflected the impact of the supplementation. No clinically significant alterations in fatty acid levels or metabolism were identified. After discontinuing study formula and consuming a diet without DHA or ARA for about 3 months, no differences in fatty acid levels among formula fed groups were detectable, except for phosphatidylethanolamine levels of 18:2 (range 8.9-9.3%) and DHA (range 3.2-4.1%) which differences were not identified as being clinically significant. However, the breast fed group shows statistically significant differences in 13 fatty acid levels compared to the formula fed infants. These differences are undoubtedly due to the differences in fatty acid composition of human milk and the term formulas including the lack of DHA and ARA in the latter.

Preterm infant complications were similar in all groups (See table

11). Over 80% of all infants were opthamologically examined and over 90% had ultrasound evaluation of their heads. Specifically, the incidence and severity of retinopathy of prematurity (ROP or retrolental fibroplasia/RLF) and the incidence of intraventricular hemorrhage or its complications did not differ among formula groups. No feeding group related complications were identified.

Serious adverse experiences did not differ ($p = 0.93$) among the formula groups and were in the range of those expected in a premature infant population while on study formula: 6% in group C, 5% in group D, and 6% in group DA (See table 12). After the experimental formula phase, serious adverse experiences still did not differ among the preterm groups (See table 13): 13% in group C, 15% in group D, and 15% in group DA. However, the term infant breast fed group had significantly fewer serious adverse experiences (1%, $p = 0.002$) as expected. Two infants reportedly suffered sudden infant death syndrome (SIDS), one in group C and one in group D; there was no significant difference in this complication among all four groups.

Conclusions:

We conclude that feeding 0.13% of calories as DHA from micro algal oil and feeding 0.13% of calories as DHA from micro algal oil plus 0.26% of calories as ARA from fungal oil in the matrix of premature infant formula to premature infants during the period of their initial hospitalization prior to 40 weeks post conceptual age is safe. These micro algal and fungal oil supplements do not result in any adverse effect on growth, clinical complications, or untoward events. Furthermore, this study reveals that growth benefits accrue to premature infants fed Enfamil Premature Formula supplemented with DHA and ARA from these sources compared to unsupplemented formula or formula supplemented with only DHA. No measurable benefit on visual acuity was identified when infants were tested at about 3 and 5 months after the supplemented formula was discontinued (2 and 4 months corrected age). However, providing human milk levels of intake of long chain polyunsaturated acids are warranted

because they are critical to brain development and foster enhanced catch-up growth during this early development period.

Table 1
Birth Statistics of Premature Subjects

	n	Mean (std)	Range	p-value
Post-Conceptual Age (Weeks)				
Control	62	29.5 (1.7)	25 - 33	
DHA	66	30.0 (1.4)	26 - 32	0.076
DHA+ARA	66	29.7 (1.7)	26 - 34	
Birth Weight (g)				
Control	62	1233.1 (176.6)	846 - 1560	
DHA	66	1272.8 (168.1)	900 - 1545	0.25
DHA+ARA	66	1278.9 (177.6)	910 - 1535	
Birth Length (cm)				
Control	60	38.4 (2.3)	34 - 43.75	
DHA	66	38.6 (2.2)	33 - 43.5	0.62
DHA+ARA	66	38.7 (2.3)	33 - 44	
Birth Head Circumference (cm)				
Control	61	26.9 (1.5)	23.5 - 30.5	
DHA	64	27.3 (2.1)	22 - 37	0.53
DHA+ARA	65	27.2 (1.6)	23.5 - 30	

Table 2
Summary of Final Study Status

	Regimen				p-value
	Control	DHA	DHA+ARA	HM	
Immediate dropout, study formula never consumed		2	2		
Study Formula Phase *					
Completed	52 (84%)	59 (89%)	62 (94%)		0.20
Discontinued	10 (16%)	7 (11%)	4 (6%)		
Reason discontinued					
>96 cumulative hours NPO	3	1			
<28 days of intake >= 90 kcal/kg/day	3	3			
Complications unrelated to study formula	1				
NEC or other GI disease		1	1		
Formula intolerance			1		
Parents request	2	2	1		
Not off oxygen prior to discharge			1		
Protocol violation	1				
Term Formula Phase **					
Completed	45 (87%)	47 (80%)	53 (85%)	77 (86%)	0.74
Discontinued	7 (13%)	12 (20%)	9 (15%)	13 (14%)	

*The CRFs for 9709-003 (DHA) and 9743-304 (DHA) were marked discontinued because the subjects met the study formula intake criteria for only 27 days. These subjects are counted completed here because subjects at other sites with similar intakes were marked completed.
**Based on subjects who completed the Study Formula phase. During the Term Formula phase, subjects were fed marketed formula. Switching to a different marketed formula did not result in termination from the Term Formula phase.

Table 3

Weight Growth Rate During Study Formula Phase

Regimen	n	Least Square Mean	Standard Error	Comparison	Comparison p-value*	Study p-value	Gender p-value	Gender-by-Regimen p-value
Control	60	30.7	1.1	Control vs DHA	0.967	0.00	0.17	0.87
DHA	65	33.3	1.1	Control vs DHA+ARA	0.998			
DHA+ARA	66	34.7	1.1					

* One-sided test of the null hypothesis: Test Mean >= Control Mean

Table 4

Weight at 40, 48, and 57 Weeks Post-Conceptual Age

Weeks Post-Conceptual Age	Regimen	n	Least Square Mean	Standard Error	Comparison	Comparison p-value*	Study p-value	Gender p-value	Gender-by-Regimen p-value
40	Control	52	3075.3	67.9	Control vs DHA	0.388	0.59	0.45	1.00
	DHA	54	3051.4	66.8	Control vs DHA+ARA	0.931			
	DHA+ARA	59	3198.2	62.9	HM vs DHA	0.000			
	HM	90	3437.7	60.6	HM vs DHA+ARA	0.001			
					HM vs Control	0.000			
48	Control	53	4711.0	94.6	Control vs DHA	0.360	0.58	0.13	0.29
	DHA	51	4663.8	97.3	Control vs DHA+ARA	0.995			
	DHA+ARA	57	5039.1	93.0	HM vs DHA	0.000			
	HM	81	5181.5	85.9	HM vs DHA+ARA	0.114			
					HM vs Control	0.000			
57	Control	47	6045.4	139.5	Control vs DHA	0.371	0.58	0.29	0.33
	DHA	49	5987.2	137.6	Control vs DHA+ARA	0.940			
	DHA+ARA	55	6312.9	127.9	HM vs DHA	0.005			
	HM	76	6405.0	126.7	HM vs DHA+ARA	0.278			
					HM vs Control	0.014			

* One-sided test of the null hypothesis: Test Mean >= Control Mean

Table 5

Post-hoc Analysis of Weight

Time	Comparison	Two-sided p-value
Weight Gain During Study Formula Phase	C vs. DHA	0.067
	C vs. DHA+ARA	0.004
	DHA vs. DHA+ARA	0.30
Weight at 40 Weeks pca	C vs. DHA	0.78
	C vs. DHA+ARA	0.14
	DHA vs. DHA+ARA	0.074
	HM vs. DHA	<0.001
	HM vs. DHA+ARA	0.002
	HM vs. C	<0.001
Weight at 48 Weeks pca	C vs. DHA	0.72
	C vs. DHA+ARA	0.011
	DHA vs. DHA+ARA	0.004
	HM vs. DHA	<0.001
	HM vs. DHA+ARA	0.23
	HM vs. C	<0.001
Weight at 57 Weeks pca	C vs. DHA	0.74
	C vs. DHA+ARA	0.12
	DHA vs. DHA+ARA	0.057
	HM vs. DHA	0.010
	HM vs. DHA+ARA	0.56
	HM vs. C	0.028

Table 6

Length at 40, 48, and 57 Weeks Post-Conceptual Age

Weeks Post-Conceptual Age	Regimen	n	Least Square Mean	Standard Error	Regimen p-value	Pairwise Comparison	Pairwise p-value	Study p-value	Gender p-value	Gender-by-Regimen p-value
40	Control	52	48.4	0.4	0.000	Control vs DHA	0.242	0.03	0.88	0.63
	DHA	54	47.8	0.4		Control vs DHA+ARA	0.233			
	DHA+ARA	58	49.0	0.4		HM vs DHA	0.000			
	HM	89	50.6	0.4		HM vs DHA+ARA	0.000			
						Control vs HM	0.000			
						DHA vs DHA+ARA	0.017			
48	Control	53	54.7	0.3	0.000	Control vs DHA	0.824	0.00	0.14	0.52
	DHA	52	54.6	0.3		Control vs DHA+ARA	0.079			
	DHA+ARA	57	55.5	0.3		HM vs DHA	0.000			
	HM	81	57.4	0.3		HM vs DHA+ARA	0.000			
						Control vs HM	0.000			
						DHA vs DHA+ARA	0.050			
57	Control	47	60.7	0.4	0.000	Control vs DHA	0.615	0.00	0.02	0.84
	DHA	49	60.5	0.4		Control vs DHA+ARA	0.236			
	DHA+ARA	54	61.3	0.3		HM vs DHA	0.000			
	HM	76	62.4	0.3		HM vs DHA+ARA	0.006			
						Control vs HM	0.000			
						DHA vs DHA+ARA	0.087			

Table 7

Head Circumference at 40, 48, and 57 Weeks Post-Conceptual Age

Weeks Post-Conceptual Age	Regimen	n	Least Square Mean	Standard Error	Regimen p-value	Pairwise Comparison	Pairwise p-value	Study p-value	Gender p-value	Gender-by-Regimen p-value
40	Control	51	35.4	0.2	0.000	Control vs DHA	0.931	0.91	0.00	0.38
	DHA	53	35.4	0.2		Control vs DHA+ARA	0.900			
	DHA+ARA	58	35.5	0.2		HM vs DHA	0.000			
	HM	85	34.5	0.2		HM vs DHA+ARA	0.000			
						Control vs HM	0.000			
						DHA vs DHA+ARA	0.829			
48	Control	52	39.1	0.2	0.983			0.81	0.00	1.00
	DHA	51	39.0	0.2						
	DHA+ARA	56	39.0	0.2						
	HM	81	39.0	0.1						
57	Control	47	41.9	0.2	0.689			0.64	0.00	0.85
	DHA	49	41.6	0.2						
	DHA+ARA	53	41.7	0.2						
	HM	76	41.7	0.2						

Table 8

Visual Acuity at 48 and 57 Weeks Post-Conceptual Age

Weeks Post-Conceptual Age	Regimen	n	Geometric mean (cycles/deg)	Least Square Mean (log base2 cycles/deg)	Standard Error (octaves)	Regimen p-value	Pairwise Comparison	Pairwise p-value	Study p-value
48	Control	51	1.72	0.78	0.10	0.950			0.000
	DHA	50	1.80	0.85	0.10				
	DHA+ARA	57	1.72	0.78	0.09				
	HM	81	1.75	0.81	0.09				
57	Control	46	3.47	1.79	0.08	0.004	Control vs DHA	0.697	0.000
	DHA	47	3.37	1.75	0.08		Control vs DHA+ARA	0.071	
	DHA+ARA	55	3.06	1.61	0.07		HM vs DHA	0.042	
	HM	77	3.85	1.94	0.07		HM vs DHA+ARA	0.000	
							Control vs HM	0.113	
							DHA vs DHA+ARA	0.158	

Table 9

Red Blood Cell Phosphatidylcholine Fatty Acids

Time	Fatty Acid	Regimen	n	Arithmetic Mean	Standard Error	Median	Regimen p-value	Pairwise Comparison	Pairwise p-value
Study Form Initiation	12:0	Control	52	0.081	0.019	0.036	0.762		
		DHA	58	0.066	0.013	0.030			
		DHA+ARA	61	0.057	0.009	0.031			
Study Form Initiation	14:0	Control	52	0.623	0.036	0.599	0.559		
		DHA	58	0.663	0.031	0.686			
		DHA+ARA	61	0.661	0.031	0.656			
Study Form Initiation	14:1	Control	52	0.045	0.009	0.021	0.165		
		DHA	58	0.026	0.005	0.016			
		DHA+ARA	61	0.035	0.006	0.018			
Study Form Initiation	16:0	Control	52	36.706	0.540	36.594	0.884		
		DHA	58	36.363	0.462	35.578			
		DHA+ARA	61	36.877	0.445	35.987			
Study Form Initiation	16:1	Control	52	0.940	0.049	0.845	0.441		
		DHA	58	0.981	0.050	0.976			
		DHA+ARA	61	1.094	0.064	0.931			
Study Form Initiation	18:0	Control	52	11.660	0.243	11.468	0.243		
		DHA	58	11.402	0.238	11.201			
		DHA+ARA	61	11.016	0.192	11.174			
Study Form Initiation	18:1	Control	52	17.053	0.298	17.308	0.679		
		DHA	58	17.219	0.391	16.935			
		DHA+ARA	61	17.256	0.271	16.988			
Study Form Initiation	18:2	Control	52	18.614	0.525	18.952	0.830		
		DHA	58	18.631	0.505	19.603			
		DHA+ARA	61	18.573	0.466	18.824			
Study Form Initiation	18:3n6	Control	52	0.120	0.008	0.116	0.034	Control vs DHA	0.196
		DHA	58	0.136	0.008	0.130		Control vs DHA+ARA	0.010
		DHA+ARA	61	0.150	0.009	0.134		DHA vs DHA+ARA	0.176

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Time	Fatty Acid	Regimen	n	Arithmetic Mean	Standard Error	Median	Regimen p-value	Pairwise Comparison	Pairwise p-value
Study Form Initiation	20:0	Control	52	0.399	0.050	0.224	0.647		
		DHA	58	0.337	0.035	0.236			
		DHA+ARA	61	0.310	0.037	0.188			
Study Form Initiation	18:3n3	Control	52	0.315	0.033	0.246	0.234		
		DHA	58	0.257	0.014	0.246			
		DHA+ARA	61	0.233	0.010	0.216			
Study Form Initiation	20:1	Control	52	0.287	0.020	0.262	0.723		
		DHA	58	0.287	0.015	0.281			
		DHA+ARA	61	0.268	0.011	0.269			
Study Form Initiation	18:4	Control	52	0.017	0.003	0.000	0.290		
		DHA	58	0.025	0.004	0.017			
		DHA+ARA	61	0.017	0.003	0.008			
Study Form Initiation	20:2n6	Control	52	0.632	0.025	0.632	0.673		
		DHA	58	0.628	0.025	0.640			
		DHA+ARA	61	0.602	0.021	0.614			
Study Form Initiation	20:3n6	Control	52	2.144	0.098	2.096	0.507		
		DHA	58	2.208	0.080	2.296			
		DHA+ARA	61	2.218	0.074	2.135			
Study Form Initiation	20:4n6	Control	52	7.657	0.262	8.124	0.819		
		DHA	58	8.164	0.347	7.876			
		DHA+ARA	61	8.090	0.310	8.207			
Study Form Initiation	22:1	Control	52	0.106	0.010	0.105	0.155		
		DHA	58	0.127	0.010	0.130			
		DHA+ARA	61	0.126	0.010	0.139			
Study Form Initiation	20:5n3	Control	52	0.351	0.057	0.298	0.911		
		DHA	58	0.322	0.015	0.302			
		DHA+ARA	61	0.321	0.015	0.329			

Table 9

Red Blood Cell Phosphatidylcholine Fatty Acids

Time	Fatty Acid	Regimen	n	Arithmetic Mean	Standard Error	Median	Regimen p-value	Pairwise Comparison	Pairwise p-value
Study Form Initiation	22:4n6	Control	52	0.578	0.144	0.423	0.331		
		DHA	58	0.493	0.030	0.481			
		DHA+ARA	61	0.443	0.021	0.425			
Study Form Initiation	24:1	Control	52	0.208	0.054	0.075	0.665		
		DHA	58	0.115	0.019	0.084			
		DHA+ARA	61	0.180	0.056	0.096			
Study Form Initiation	22:5n6	Control	52	0.266	0.020	0.232	0.923		
		DHA	58	0.259	0.017	0.239			
		DHA+ARA	61	0.265	0.018	0.256			
Study Form Initiation	22:4n3	Control	52	0.000	0.000	0.000	0.199		
		DHA	58	0.001	0.001	0.000			
		DHA+ARA	61	0.002	0.001	0.000			
Study Form Initiation	22:5n3	Control	52	0.213	0.019	0.203	0.885		
		DHA	58	0.215	0.013	0.195			
		DHA+ARA	61	0.203	0.010	0.193			
Study Form Initiation	22:6n3	Control	52	0.984	0.051	1.000	0.858		
		DHA	58	1.075	0.053	1.034			
		DHA+ARA	61	1.006	0.050	0.970			

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Red Blood Cell Phosphatidylcholine Fatty Acids

Time	Fatty Acid	Regimen	n	Arithmetic Mean	Standard Error	Median	Regimen p-value	Pairwise Comparison	Pairwise p-value
Study Form Termination	12:0	Control	53	0.100	0.026	0.035	0.843		
		DHA	56	0.111	0.042	0.031			
		DHA+ARA	59	0.064	0.012	0.032			
Study Form Termination	14:0	Control	53	0.808	0.039	0.806	0.834		
		DHA	56	0.781	0.035	0.783			
		DHA+ARA	59	0.755	0.036	0.758			
Study Form Termination	14:1	Control	53	0.047	0.008	0.033	0.155		
		DHA	56	0.036	0.009	0.015			
		DHA+ARA	59	0.036	0.007	0.018			
Study Form Termination	16:0	Control	53	35.837	0.512	34.798	0.767		
		DHA	56	35.560	0.595	34.841			
		DHA+ARA	59	35.069	0.584	33.890			
Study Form Termination	16:1	Control	53	0.566	0.026	0.526	0.013	Control vs DHA	0.118
		DHA	56	0.594	0.042	0.475		Control vs DHA+ARA	0.003
		DHA+ARA	59	0.526	0.029	0.472		DHA vs DHA+ARA	0.152
Study Form Termination	18:0	Control	53	13.972	0.261	14.197	0.886		
		DHA	56	14.065	0.237	13.867			
		DHA+ARA	59	14.341	0.253	14.108			
Study Form Termination	18:1	Control	53	14.456	0.277	14.291	0.686		
		DHA	56	14.116	0.272	13.998			
		DHA+ARA	59	14.344	0.380	14.218			
Study Form Termination	18:2	Control	53	21.673	0.340	21.506	0.001	Control vs DHA	0.600
		DHA	56	22.045	0.457	22.517		Control vs DHA+ARA	0.005
		DHA+ARA	59	19.899	0.337	20.662		DHA vs DHA+ARA	0.001
Study Form Termination	18:3n6	Control	53	0.080	0.006	0.074	0.527		
		DHA	56	0.088	0.009	0.076			
		DHA+ARA	59	0.087	0.013	0.066			

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Time	Fatty Acid	Regimen	n	Arithmetic Mean	Standard Error	Median	Regimen p-value	Pairwise Comparison	Pairwise p-value
Study Form Termination	20:0	Control	53	0.504	0.050	0.392	0.424		
		DHA	56	0.472	0.053	0.281			
		DHA+ARA	59	0.430	0.049	0.251			
Study Form Termination	18:3n3	Control	53	0.321	0.020	0.283	0.031	Control vs DHA	0.503
		DHA	56	0.335	0.030	0.285		Control vs DHA+ARA	0.068
		DHA+ARA	59	0.273	0.009	0.256		DHA vs DHA+ARA	0.011
Study Form Termination	20:1	Control	53	0.318	0.014	0.302	0.149		
		DHA	56	0.300	0.013	0.283			
		DHA+ARA	59	0.307	0.013	0.283			
Study Form Termination	18:4	Control	53	0.022	0.004	0.015	0.672		
		DHA	56	0.022	0.003	0.018			
		DHA+ARA	59	0.014	0.002	0.008			
Study Form Termination	20:2n6	Control	53	0.893	0.026	0.910	0.051		
		DHA	56	0.880	0.023	0.873			
		DHA+ARA	59	0.824	0.022	0.821			
Study Form Termination	20:3n6	Control	53	2.032	0.073	2.091	0.208		
		DHA	56	2.017	0.070	2.043			
		DHA+ARA	59	1.908	0.064	1.904			
Study Form Termination	20:4n6	Control	53	6.046	0.240	6.029	0.000	Control vs DHA	0.097
		DHA	56	5.774	0.220	5.892		Control vs DHA+ARA	0.000
		DHA+ARA	59	8.465	0.255	8.891		DHA vs DHA+ARA	0.000
Study Form Termination	22:1	Control	53	0.117	0.010	0.125	0.946		
		DHA	56	0.110	0.009	0.114			
		DHA+ARA	59	0.115	0.011	0.104			
Study Form Termination	20:5n3	Control	53	0.214	0.022	0.189	0.000	Control vs DHA	0.004
		DHA	56	0.246	0.012	0.233		Control vs DHA+ARA	0.108
		DHA+ARA	59	0.186	0.014	0.169		DHA vs DHA+ARA	0.000

Table 9

Red Blood Cell Phosphatidylcholine Fatty Acids

Time	Fatty Acid	Regimen	n	Arithmetic Mean	Standard Error	Median	Regimen p-value	Pairwise Comparison	Pairwise p-value
Study Form Termination	22:4n6	Control	53	0.484	0.048	0.390	0.093		
		DHA	56	0.489	0.061	0.426			
		DHA+ARA	59	0.496	0.027	0.487			
Study Form Termination	24:1	Control	53	0.127	0.039	0.062	0.303		
		DHA	56	0.143	0.036	0.086			
		DHA+ARA	59	0.177	0.040	0.089			
Study Form Termination	22:5n6	Control	53	0.181	0.013	0.163	0.006	Control vs DHA	0.005
		DHA	56	0.145	0.011	0.133		Control vs DHA+ARA	0.895
		DHA+ARA	59	0.172	0.009	0.165		DHA vs DHA+ARA	0.006
Study Form Termination	22:4n3	Control	53	0.001	0.001	0.000	0.359		
		DHA	56	0.001	0.001	0.000			
		DHA+ARA	59	0.003	0.002	0.000			
Study Form Termination	22:5n3	Control	53	0.306	0.019	0.289	0.221		
		DHA	56	0.293	0.026	0.260			
		DHA+ARA	59	0.265	0.013	0.255			
Study Form Termination	22:6n3	Control	53	0.895	0.072	0.812	0.000	Control vs DHA	0.000
		DHA	56	1.380	0.063	1.352		Control vs DHA+ARA	0.000
		DHA+ARA	59	1.244	0.049	1.259		DHA vs DHA+ARA	0.141

Table 9

Red Blood Cell Phosphatidylcholine Fatty Acids

Time	Fatty Acid	Regimen	n	Arithmetic Mean	Standard Error	Median	Regimen p-value	Pairwise Comparison	Pairwise p-value
48 Weeks PCA	12:0	Control	37	0.032	0.005	0.026	0.729		
		DHA	32	0.028	0.006	0.016			
		DHA+ARA	38	0.026	0.004	0.021			
		HM	56	0.059	0.016	0.020			
48 Weeks PCA	14:0	Control	37	0.402	0.039	0.331	0.943		
		DHA	32	0.353	0.032	0.324			
		DHA+ARA	38	0.353	0.024	0.328			
		HM	56	0.381	0.026	0.335			
48 Weeks PCA	14:1	Control	37	0.025	0.006	0.013	0.448		
		DHA	32	0.026	0.007	0.011			
		DHA+ARA	38	0.026	0.006	0.015			
		HM	56	0.024	0.003	0.020			
48 Weeks PCA	16:0	Control	37	34.627	0.577	34.319	0.000	Control vs DHA	0.527
		DHA	32	35.272	0.689	34.473		Control vs DHA+ARA	0.593
		DHA+ARA	38	34.802	0.506	34.165		HM vs DHA	0.000
		HM	56	33.037	0.506	32.228		HM vs DHA+ARA	0.000
								Control vs HM	0.000
								DHA vs DHA+ARA	0.906
48 Weeks PCA	16:1	Control	37	0.435	0.043	0.338	0.000	Control vs DHA	0.524
		DHA	32	0.380	0.023	0.352		Control vs DHA+ARA	0.467
		DHA+ARA	38	0.395	0.024	0.368		HM vs DHA	0.000
		HM	56	0.507	0.020	0.473		HM vs DHA+ARA	0.006
								Control vs HM	0.000
								DHA vs DHA+ARA	0.183

Table 9

Red Blood Cell Phosphatidylcholine Fatty Acids

Time	Fatty Acid	Regimen	n	Arithmetic Mean	Standard Error	Median	Regimen p-value	Pairwise Comparison	Pairwise p-value
48 Weeks PCA	18:0	Control	37	13.016	0.313	12.759	0.000	Control vs DHA	0.760
		DHA	32	12.944	0.249	12.786		Control vs DHA+ARA	0.889
		DHA+ARA	38	12.804	0.235	12.793		HM vs DHA	0.000
		HM	56	14.583	0.287	14.729		HM vs DHA+ARA	0.000
								Control vs HM	0.000
								DHA vs DHA+ARA	0.661
48 Weeks PCA	18:1	Control	37	17.894	0.453	18.636	0.256		
		DHA	32	17.766	0.429	18.492			
		DHA+ARA	38	17.850	0.289	18.227			
		HM	56	18.662	0.305	18.727			
48 Weeks PCA	18:2	Control	37	23.469	0.518	23.552	0.000	Control vs DHA	0.840
		DHA	32	23.538	0.516	23.717		Control vs DHA+ARA	0.527
		DHA+ARA	38	23.738	0.422	23.839		HM vs DHA	0.000
		HM	56	18.650	0.344	18.482		HM vs DHA+ARA	0.000
								Control vs HM	0.000
								DHA vs DHA+ARA	0.685
48 Weeks PCA	18:3n6	Control	37	0.071	0.008	0.061	0.002	Control vs DHA	0.950
		DHA	32	0.069	0.005	0.067		Control vs DHA+ARA	0.774
		DHA+ARA	38	0.069	0.006	0.062		HM vs DHA	0.004
		HM	56	0.042	0.004	0.039		HM vs DHA+ARA	0.001
								Control vs HM	0.003
								DHA vs DHA+ARA	0.831
48 Weeks PCA	20:0	Control	37	0.348	0.075	0.197	0.785		
		DHA	32	0.339	0.061	0.206			
		DHA+ARA	38	0.304	0.061	0.172			
		HM	56	0.409	0.044	0.215			

Table 9

Red Blood Cell Phosphatidylcholine Fatty Acids

Time	Fatty Acid	Regimen	n	Arithmetic Mean	Standard Error	Median	Regimen p-value	Pairwise Comparison	Pairwise p-value
48 Weeks PCA	18:3n3	Control	37	0.222	0.019	0.182	0.001	Control vs DHA	0.812
		DHA	32	0.211	0.015	0.182		Control vs DHA+ARA	0.918
		DHA+ARA	38	0.203	0.010	0.190		HM vs DHA	0.001
		HM	56	0.182	0.022	0.120		HM vs DHA+ARA	0.002
								Control vs HM	0.001
								DHA vs DHA+ARA	0.737
48 Weeks PCA	20:1	Control	37	0.418	0.019	0.420	0.000	Control vs DHA	0.579
		DHA	32	0.406	0.025	0.435		Control vs DHA+ARA	0.588
		DHA+ARA	38	0.382	0.016	0.375		HM vs DHA	0.001
		HM	56	0.311	0.014	0.309		HM vs DHA+ARA	0.001
								Control vs HM	0.000
								DHA vs DHA+ARA	0.974
48 Weeks PCA	18:4	Control	37	0.018	0.005	0.000	0.010	Control vs DHA	0.822
		DHA	32	0.016	0.004	0.000		Control vs DHA+ARA	0.161
		DHA+ARA	38	0.007	0.002	0.000		HM vs DHA	0.039
		HM	56	0.024	0.004	0.015		HM vs DHA+ARA	0.001
								Control vs HM	0.054
								DHA vs DHA+ARA	0.262
48 Weeks PCA	20:2n6	Control	37	0.543	0.023	0.537	0.629		
		DHA	32	0.557	0.032	0.543			
		DHA+ARA	38	0.636	0.053	0.550			
		HM	56	0.560	0.014	0.531			
48 Weeks PCA	20:3n6	Control	37	1.709	0.086	1.741	0.000	Control vs DHA	0.610
		DHA	32	1.702	0.073	1.684		Control vs DHA+ARA	0.735
		DHA+ARA	38	1.844	0.090	1.717		HM vs DHA	0.000
		HM	56	2.265	0.086	2.166		HM vs DHA+ARA	0.000
								Control vs HM	0.000
								DHA vs DHA+ARA	0.405

Table 9

Red Blood Cell Phosphatidylcholine Fatty Acids

Time	Fatty Acid	Regimen	n	Arithmetic Mean	Standard Error	Median	Regimen p-value	Pairwise Comparison	Pairwise p-value
48 Weeks PCA	20:4n6	Control	37	4.738	0.255	4.736	0.000	Control vs DHA	0.508
		DHA	32	4.475	0.196	4.499		Control vs DHA+ARA	0.805
		DHA+ARA	38	4.550	0.185	4.746		HM vs DHA	0.000
		HM	56	7.408	0.250	7.666		HM vs DHA+ARA	0.000
								Control vs HM	0.000
								DHA vs DHA+ARA	0.672
48 Weeks PCA	22:1	Control	37	0.166	0.036	0.131	0.664		
		DHA	32	0.116	0.014	0.118			
		DHA+ARA	38	0.131	0.024	0.105			
		HM	56	0.160	0.030	0.104			
48 Weeks PCA	20:5n3	Control	37	0.102	0.015	0.077	0.000	Control vs DHA	0.633
		DHA	32	0.084	0.006	0.083		Control vs DHA+ARA	0.086
		DHA+ARA	38	0.099	0.009	0.078		HM vs DHA	0.000
		HM	56	0.138	0.009	0.123		HM vs DHA+ARA	0.000
								Control vs HM	0.000
								DHA vs DHA+ARA	0.239
48 Weeks PCA	22:4n6	Control	37	0.426	0.059	0.373	0.244		
		DHA	32	0.382	0.029	0.417			
		DHA+ARA	38	0.440	0.054	0.384			
		HM	56	0.406	0.022	0.377			
48 Weeks PCA	24:1	Control	37	0.247	0.070	0.112	0.000	Control vs DHA	0.337
		DHA	32	0.210	0.062	0.116		Control vs DHA+ARA	0.247
		DHA+ARA	38	0.179	0.055	0.108		HM vs DHA	0.000
		HM	56	0.115	0.020	0.079		HM vs DHA+ARA	0.000
								Control vs HM	0.000
								DHA vs DHA+ARA	0.878

Table 9

Red Blood Cell Phosphatidylcholine Fatty Acids

Time	Fatty Acid	Regimen	n	Arithmetic Mean	Standard Error	Median	Regimen p-value	Pairwise Comparison	Pairwise p-value
48 Weeks PCA	22:5n6	Control	37	0.210	0.016	0.212	0.000	Control vs DHA	0.505
		DHA	32	0.189	0.012	0.186		Control vs DHA+ARA	0.647
		DHA+ARA	38	0.231	0.022	0.198		HM vs DHA	0.000
		HM	56	0.264	0.016	0.265		HM vs DHA+ARA	0.001
								Control vs HM	0.000
								DHA vs DHA+ARA	0.270
48 Weeks PCA	22:4n3	Control	37	0.000	0.000	0.000	1.000		
		DHA	32	0.000	0.000	0.000			
		DHA+ARA	38	0.000	0.000	0.000			
		HM	56	0.000	0.000	0.000			
48 Weeks PCA	22:5n3	Control	37	0.286	0.029	0.260	0.000	Control vs DHA	0.598
		DHA	32	0.253	0.017	0.251		Control vs DHA+ARA	0.759
		DHA+ARA	38	0.268	0.026	0.256		HM vs DHA	0.000
		HM	56	0.339	0.018	0.314		HM vs DHA+ARA	0.000
								Control vs HM	0.000
								DHA vs DHA+ARA	0.817
48 Weeks PCA	22:6n3	Control	37	0.595	0.047	0.569	0.000	Control vs DHA	0.111
		DHA	32	0.685	0.048	0.676		Control vs DHA+ARA	0.052
		DHA+ARA	38	0.662	0.043	0.663		HM vs DHA	0.000
		HM	56	1.475	0.081	1.333		HM vs DHA+ARA	0.000
								Control vs HM	0.000
								DHA vs DHA+ARA	0.776

Table 10

Red Blood Cell Phosphatidylethanolamine Fatty Acids

Time	Fatty Acid	Regimen	n	Arithmetic Mean	Standard Error	Median	Regimen p-value	Pairwise Comparison	Pairwise p-value
Study Form Initiation	12:0	Control	52	0.069	0.015	0.022	0.546		
		DHA	57	0.075	0.013	0.033			
		DHA+ARA	61	0.063	0.010	0.039			
Study Form Initiation	14:0	Control	52	0.307	0.038	0.220	0.792		
		DHA	57	0.278	0.025	0.206			
		DHA+ARA	61	0.277	0.021	0.246			
Study Form Initiation	14:1	Control	52	0.080	0.015	0.032	0.181		
		DHA	57	0.061	0.012	0.028			
		DHA+ARA	61	0.062	0.009	0.050			
Study Form Initiation	16:0	Control	52	20.021	0.736	17.945	0.967		
		DHA	57	19.847	0.622	19.295			
		DHA+ARA	61	19.796	0.451	19.035			
Study Form Initiation	16:1	Control	52	0.731	0.035	0.698	0.337		
		DHA	57	0.769	0.034	0.746			
		DHA+ARA	61	0.836	0.035	0.837			
Study Form Initiation	18:0	Control	52	8.857	0.329	8.469	0.142		
		DHA	57	8.434	0.227	8.308			
		DHA+ARA	61	8.201	0.215	7.904			
Study Form Initiation	18:1	Control	52	16.450	0.301	16.698	0.412		
		DHA	57	16.208	0.326	16.308			
		DHA+ARA	61	16.415	0.375	16.001			
Study Form Initiation	18:2	Control	52	6.615	0.253	6.682	0.773		
		DHA	57	6.336	0.280	6.346			
		DHA+ARA	61	6.175	0.294	5.682			
Study Form Initiation	18:3n6	Control	52	0.165	0.018	0.145	0.040	Control vs DHA	0.373
		DHA	57	0.190	0.019	0.152		Control vs DHA+ARA	0.013
		DHA+ARA	61	0.192	0.016	0.169		DHA vs DHA+ARA	0.101

Table 10

Red Blood Cell Phosphatidylethanolamine Fatty Acids

Time	Fatty Acid	Regimen	n	Arithmetic Mean	Standard Error	Median	Regimen p-value	Pairwise Comparison	Pairwise p-value
Study Form Initiation	20:0	Control	52	0.372	0.043	0.291	0.151		
		DHA	57	0.314	0.030	0.244			
		DHA+ARA	61	0.259	0.024	0.186			
Study Form Initiation	18:3n3	Control	52	0.305	0.023	0.261	0.641		
		DHA	57	0.269	0.018	0.249			
		DHA+ARA	61	0.257	0.016	0.225			
Study Form Initiation	20:1	Control	52	0.573	0.036	0.517	0.395		
		DHA	57	0.615	0.034	0.555			
		DHA+ARA	61	0.571	0.027	0.544			
Study Form Initiation	18:4	Control	52	0.025	0.005	0.000	0.371		
		DHA	57	0.031	0.004	0.025			
		DHA+ARA	61	0.030	0.007	0.021			
Study Form Initiation	20:2n6	Control	52	0.479	0.023	0.480	0.706		
		DHA	57	0.463	0.024	0.437			
		DHA+ARA	61	0.443	0.028	0.427			
Study Form Initiation	20:3n6	Control	52	1.843	0.072	1.829	0.099		
		DHA	57	1.965	0.077	1.820			
		DHA+ARA	61	1.973	0.064	1.911			
Study Form Initiation	20:4n6	Control	52	25.817	0.618	26.820	0.353		
		DHA	57	26.475	0.611	27.376			
		DHA+ARA	61	26.747	0.645	27.708			
Study Form Initiation	22:1	Control	52	0.150	0.017	0.138	0.572		
		DHA	57	0.167	0.015	0.151			
		DHA+ARA	61	0.168	0.017	0.141			
Study Form Initiation	20:5n3	Control	52	0.378	0.024	0.357	0.997		
		DHA	57	0.384	0.024	0.370			
		DHA+ARA	61	0.366	0.022	0.335			

Table 10

Red Blood Cell Phosphatidylethanolamine Fatty Acids

Time	Fatty Acid	Regimen	n	Arithmetic Mean	Standard Error	Median	Regimen p-value	Pairwise Comparison	Pairwise p-value
Study Form Initiation	22:4n6	Control	52	7.290	0.182	7.402	0.875		
		DHA	57	7.431	0.186	7.638			
		DHA+ARA	61	7.456	0.167	7.270			
Study Form Initiation	24:1	Control	52	0.100	0.028	0.041	0.068		
		DHA	57	0.059	0.009	0.031			
		DHA+ARA	61	0.072	0.010	0.047			
Study Form Initiation	22:5n6	Control	52	1.757	0.083	1.782	0.555		
		DHA	57	1.809	0.070	1.857			
		DHA+ARA	61	1.851	0.075	1.775			
Study Form Initiation	22:4n3	Control	52	0.001	0.001	0.000	0.257		
		DHA	57	0.001	0.001	0.000			
		DHA+ARA	61	0.005	0.002	0.000			
Study Form Initiation	22:5n3	Control	52	1.496	0.109	1.308	0.195		
		DHA	57	1.375	0.109	0.988			
		DHA+ARA	61	1.380	0.097	1.041			
Study Form Initiation	22:6n3	Control	52	6.119	0.200	6.381	0.375		
		DHA	57	6.444	0.185	6.468			
		DHA+ARA	61	6.407	0.220	6.579			

Table 10

Red Blood Cell Phosphatidylethanolamine Fatty Acids

Time	Fatty Acid	Regimen	n	Arithmetic Mean	Standard Error	Median	Regimen p-value	Pairwise Comparison	Pairwise p-value
Study Form Termination	12:0	Control	53	0.093	0.018	0.033	0.630		
		DHA	55	0.093	0.019	0.036			
		DHA+ARA	58	0.067	0.012	0.035			
Study Form Termination	14:0	Control	53	0.360	0.031	0.279	0.782		
		DHA	55	0.380	0.039	0.265			
		DHA+ARA	58	0.348	0.030	0.256			
Study Form Termination	14:1	Control	53	0.086	0.020	0.041	0.592		
		DHA	55	0.066	0.013	0.000			
		DHA+ARA	58	0.066	0.011	0.043			
Study Form Termination	16:0	Control	53	19.326	0.673	17.617	0.560		
		DHA	55	19.062	0.614	17.556			
		DHA+ARA	58	18.357	0.467	17.568			
Study Form Termination	16:1	Control	53	0.511	0.034	0.476	0.604		
		DHA	55	0.579	0.045	0.509			
		DHA+ARA	58	0.618	0.049	0.555			
Study Form Termination	18:0	Control	53	9.614	0.266	9.406	0.024	Control vs DHA	0.130
		DHA	55	9.173	0.208	8.818		Control vs DHA+ARA	0.006
		DHA+ARA	58	8.961	0.242	8.697		DHA vs DHA+ARA	0.219
Study Form Termination	18:1	Control	53	14.763	0.437	14.695	0.333		
		DHA	55	15.177	0.299	14.927			
		DHA+ARA	58	14.814	0.330	14.499			
Study Form Termination	18:2	Control	53	9.405	0.192	9.359	0.000	Control vs DHA	0.908
		DHA	55	9.180	0.207	9.188		Control vs DHA+ARA	0.000
		DHA+ARA	58	7.756	0.141	7.586		DHA vs DHA+ARA	0.000
Study Form Termination	18:3n6	Control	53	0.169	0.012	0.163	0.160		
		DHA	55	0.187	0.017	0.157			
		DHA+ARA	58	0.198	0.018	0.161			

Table 10

Red Blood Cell Phosphatidylethanolamine Fatty Acids

Time	Fatty Acid	Regimen	n	Arithmetic Mean	Standard Error	Median	Regimen p-value	Pairwise Comparison	Pairwise p-value
Study Form Termination	20:0	Control	53	0.404	0.044	0.278	0.146		
		DHA	55	0.336	0.037	0.208			
		DHA+ARA	58	0.288	0.029	0.208			
Study Form Termination	18:3n3	Control	53	0.382	0.017	0.364	0.134		
		DHA	55	0.368	0.016	0.354			
		DHA+ARA	58	0.329	0.015	0.305			
Study Form Termination	20:1	Control	53	0.553	0.029	0.526	0.164		
		DHA	55	0.579	0.028	0.537			
		DHA+ARA	58	0.507	0.025	0.483			
Study Form Termination	18:4	Control	53	0.042	0.010	0.018	0.108		
		DHA	55	0.026	0.005	0.019			
		DHA+ARA	58	0.022	0.004	0.000			
Study Form Termination	20:2n6	Control	53	0.754	0.029	0.765	0.068		
		DHA	55	0.774	0.030	0.750			
		DHA+ARA	58	0.654	0.026	0.663			
Study Form Termination	20:3n6	Control	53	2.253	0.111	2.073	0.203		
		DHA	55	2.295	0.094	2.206			
		DHA+ARA	58	2.066	0.073	1.992			
Study Form Termination	20:4n6	Control	53	24.279	0.527	25.132	0.000	Control vs DHA	0.119
		DHA	55	23.464	0.520	24.038		Control vs DHA+ARA	0.000
		DHA+ARA	58	26.760	0.437	27.372		DHA vs DHA+ARA	0.000
Study Form Termination	22:1	Control	53	0.149	0.019	0.122	0.229		
		DHA	55	0.176	0.016	0.169			
		DHA+ARA	58	0.146	0.012	0.130			
Study Form Termination	20:5n3	Control	53	0.519	0.020	0.493	0.000	Control vs DHA	0.286
		DHA	55	0.563	0.025	0.575		Control vs DHA+ARA	0.000
		DHA+ARA	58	0.411	0.015	0.415		DHA vs DHA+ARA	0.000

Table 10

Red Blood Cell Phosphatidylethanolamine Fatty Acids

Time	Fatty Acid	Regimen	n	Arithmetic Mean	Standard Error	Median	Regimen p-value	Pairwise Comparison	Pairwise p-value
Study Form Termination	22:4n6	Control	53	7.309	0.208	7.656	0.007	Control vs DHA	0.025
		DHA	55	7.135	0.154	6.885		Control vs DHA+ARA	0.461
		DHA+ARA	58	7.592	0.155	7.635		DHA vs DHA+ARA	0.002
Study Form Termination	24:1	Control	53	0.092	0.023	0.038	0.294		
		DHA	55	0.056	0.009	0.042			
		DHA+ARA	58	0.062	0.008	0.041			
Study Form Termination	22:5n6	Control	53	1.444	0.064	1.423	0.010	Control vs DHA	0.003
		DHA	55	1.231	0.034	1.213		Control vs DHA+ARA	0.255
		DHA+ARA	58	1.347	0.040	1.330		DHA vs DHA+ARA	0.050
Study Form Termination	22:4n3	Control	53	0.000	0.000	0.000	0.137		
		DHA	55	0.004	0.002	0.000			
		DHA+ARA	58	0.004	0.002	0.000			
Study Form Termination	22:5n3	Control	53	2.694	0.110	2.839	0.003	Control vs DHA	0.004
		DHA	55	2.334	0.091	2.400		Control vs DHA+ARA	0.002
		DHA+ARA	58	2.237	0.069	2.269		DHA vs DHA+ARA	0.943
Study Form Termination	22:6n3	Control	53	4.798	0.151	4.815	0.000	Control vs DHA	0.000
		DHA	55	6.762	0.183	7.043		Control vs DHA+ARA	0.000
		DHA+ARA	58	6.389	0.150	6.498		DHA vs DHA+ARA	0.027

Table 10

Red Blood Cell Phosphatidylethanolamine Fatty Acids

Time	Fatty Acid	Regimen	n	Arithmetic Mean	Standard Error	Median	Regimen p-value	Pairwise Comparison	Pairwise p-value
48 Weeks PCA	12:0	Control	37	0.053	0.019	0.024	0.587		
		DHA	32	0.054	0.016	0.019			
		DHA+ARA	38	0.047	0.014	0.018			
		HM	56	0.045	0.011	0.023			
48 Weeks PCA	14:0	Control	37	0.243	0.030	0.169	0.598		
		DHA	32	0.251	0.041	0.162			
		DHA+ARA	38	0.235	0.025	0.188			
		HM	56	0.230	0.016	0.210			
48 Weeks PCA	14:1	Control	37	0.080	0.017	0.037	0.092		
		DHA	32	0.055	0.017	0.000			
		DHA+ARA	38	0.078	0.019	0.044			
		HM	56	0.053	0.011	0.021			
48 Weeks PCA	16:0	Control	37	17.319	0.595	16.314	0.177		
		DHA	32	17.101	0.729	15.692			
		DHA+ARA	38	17.225	0.538	16.997			
		HM	56	18.138	0.395	17.607			
48 Weeks PCA	16:1	Control	37	0.440	0.050	0.349	0.000	Control vs DHA	0.601
		DHA	32	0.390	0.035	0.336		Control vs DHA+ARA	0.524
		DHA+ARA	38	0.390	0.022	0.376		HM vs DHA	0.000
		HM	56	0.596	0.027	0.562		HM vs DHA+ARA	0.000
								Control vs HM	0.001
								DHA vs DHA+ARA	0.928

Table 10

Red Blood Cell Phosphatidylethanolamine Fatty Acids

Time	Fatty Acid	Regimen	n	Arithmetic Mean	Standard Error	Median	Regimen p-value	Pairwise Comparison	Pairwise p-value
48 Weeks PCA	18:0	Control	37	7.935	0.327	7.174	0.000	Control vs DHA	0.347
		DHA	32	7.962	0.293	7.552		Control vs DHA+ARA	0.483
		DHA+ARA	38	7.443	0.270	7.173		HM vs DHA	0.020
		HM	56	8.754	0.230	8.409		HM vs DHA+ARA	0.000
								Control vs HM	0.001
								DHA vs DHA+ARA	0.108
48 Weeks PCA	18:1	Control	37	19.438	0.368	19.410	0.038	Control vs DHA	0.401
		DHA	32	19.066	0.421	19.534		Control vs DHA+ARA	0.234
		DHA+ARA	38	19.302	0.332	19.433		HM vs DHA	0.067
		HM	56	18.469	0.278	18.141		HM vs DHA+ARA	0.118
								Control vs HM	0.005
								DHA vs DHA+ARA	0.758
48 Weeks PCA	18:2	Control	37	9.328	0.261	9.267	0.000	Control vs DHA	0.024
		DHA	32	8.867	0.210	8.696		Control vs DHA+ARA	0.187
		DHA+ARA	38	9.257	0.216	8.840		HM vs DHA	0.000
		HM	56	6.291	0.193	6.027		HM vs DHA+ARA	0.000
								Control vs HM	0.000
								DHA vs DHA+ARA	0.318
48 Weeks PCA	18:3n6	Control	37	0.198	0.020	0.182	0.050	Control vs DHA	0.879
		DHA	32	0.219	0.031	0.171		Control vs DHA+ARA	0.590
		DHA+ARA	38	0.188	0.021	0.158		HM vs DHA	0.029
		HM	56	0.129	0.012	0.112		HM vs DHA+ARA	0.061
								Control vs HM	0.014
								DHA vs DHA+ARA	0.714
48 Weeks PCA	20:0	Control	37	0.263	0.058	0.146	0.728		
		DHA	32	0.262	0.042	0.145			
		DHA+ARA	38	0.212	0.037	0.125			
		HM	56	0.295	0.031	0.240			

Table 10

Red Blood Cell Phosphatidylethanolamine Fatty Acids

Time	Fatty Acid	Regimen	n	Arithmetic Mean	Standard Error	Median	Regimen p-value	Pairwise Comparison	Pairwise p-value
48 Weeks PCA	18:3n3	Control	37	0.291	0.025	0.225	0.001	Control vs DHA	0.559
		DHA	32	0.270	0.017	0.262		Control vs DHA+ARA	0.848
		DHA+ARA	38	0.265	0.015	0.245		HM vs DHA	0.008
		HM	56	0.226	0.020	0.169		HM vs DHA+ARA	0.002
								Control vs HM	0.001
								DHA vs DHA+ARA	0.689
48 Weeks PCA	20:1	Control	37	0.715	0.031	0.648	0.000	Control vs DHA	0.339
		DHA	32	0.772	0.032	0.782		Control vs DHA+ARA	0.512
		DHA+ARA	38	0.936	0.188	0.738		HM vs DHA	0.000
		HM	56	0.533	0.024	0.492		HM vs DHA+ARA	0.000
								Control vs HM	0.000
								DHA vs DHA+ARA	0.115
48 Weeks PCA	18:4	Control	37	0.017	0.005	0.003	0.057		
		DHA	32	0.017	0.005	0.000			
		DHA+ARA	38	0.023	0.006	0.000			
		HM	56	0.027	0.004	0.019			
48 Weeks PCA	20:2n6	Control	37	0.672	0.035	0.698	0.000	Control vs DHA	0.543
		DHA	32	0.668	0.026	0.684		Control vs DHA+ARA	0.532
		DHA+ARA	38	0.715	0.032	0.689		HM vs DHA	0.000
		HM	56	0.444	0.016	0.412		HM vs DHA+ARA	0.000
								Control vs HM	0.000
								DHA vs DHA+ARA	0.995
48 Weeks PCA	20:3n6	Control	37	2.138	0.099	1.999	0.012	Control vs DHA	0.896
		DHA	32	2.165	0.100	2.045		Control vs DHA+ARA	0.935
		DHA+ARA	38	2.172	0.114	2.132		HM vs DHA	0.015
		HM	56	1.715	0.053	1.637		HM vs DHA+ARA	0.006
								Control vs HM	0.007
								DHA vs DHA+ARA	0.835

Table 10

Red Blood Cell Phosphatidylethanolamine Fatty Acids

Time	Fatty Acid	Regimen	n	Arithmetic Mean	Standard Error	Median	Regimen p-value	Pairwise Comparison	Pairwise p-value
48 Weeks PCA	20:4n6	Control	37	24.508	0.536	24.774	0.950		
		DHA	32	24.428	0.491	25.206			
		DHA+ARA	38	24.788	0.429	25.122			
		HM	56	24.625	0.384	25.189			
48 Weeks PCA	22:1	Control	37	0.168	0.016	0.172	0.121		
		DHA	32	0.189	0.022	0.188			
		DHA+ARA	38	0.154	0.022	0.133			
		HM	56	0.148	0.013	0.134			
48 Weeks PCA	20:5n3	Control	37	0.382	0.026	0.368	0.497		
		DHA	32	0.369	0.015	0.377			
		DHA+ARA	38	0.347	0.011	0.347			
		HM	56	0.384	0.016	0.360			
48 Weeks PCA	22:4n6	Control	37	8.580	0.267	8.761	0.001	Control vs DHA	0.612
		DHA	32	8.791	0.250	9.132		Control vs DHA+ARA	0.416
		DHA+ARA	38	8.576	0.188	8.472		HM vs DHA	0.000
		HM	56	7.727	0.203	7.618		HM vs DHA+ARA	0.013
								Control vs HM	0.001
								DHA vs DHA+ARA	0.199
48 Weeks PCA	24:1	Control	37	0.067	0.016	0.035	0.943		
		DHA	32	0.049	0.009	0.034			
		DHA+ARA	38	0.046	0.008	0.036			
		HM	56	0.062	0.016	0.027			

Table 10

Red Blood Cell Phosphatidylethanolamine Fatty Acids

Time	Fatty Acid	Regimen	n	Arithmetic Mean	Standard Error	Median	Regimen p-value	Pairwise Comparison	Pairwise p-value
48 Weeks PCA	22:5n6	Control	37	1.401	0.066	1.411	0.000	Control vs DHA	0.977
		DHA	32	1.353	0.057	1.414		Control vs DHA+ARA	0.997
		DHA+ARA	38	1.364	0.054	1.359		HM vs DHA	0.000
		HM	56	1.883	0.056	1.889		HM vs DHA+ARA	0.000
								Control vs HM	0.000
								DHA vs DHA+ARA	0.975
48 Weeks PCA	22:4n3	Control	37	0.000	0.000	0.000	1.000		
		DHA	32	0.000	0.000	0.000			
		DHA+ARA	38	0.000	0.000	0.000			
		HM	56	0.001	0.001	0.000			
48 Weeks PCA	22:5n3	Control	37	2.567	0.092	2.681	0.000	Control vs DHA	0.884
		DHA	32	2.561	0.086	2.630		Control vs DHA+ARA	0.148
		DHA+ARA	38	2.436	0.066	2.443		HM vs DHA	0.000
		HM	56	1.942	0.065	1.978		HM vs DHA+ARA	0.000
								Control vs HM	0.000
								DHA vs DHA+ARA	0.213
48 Weeks PCA	22:6n3	Control	37	3.196	0.159	3.013	0.000	Control vs DHA	0.000
		DHA	32	4.143	0.177	4.079		Control vs DHA+ARA	0.000
		DHA+ARA	38	3.801	0.134	3.721		HM vs DHA	0.000
		HM	56	7.283	0.201	7.341		HM vs DHA+ARA	0.000
								Control vs HM	0.000
								DHA vs DHA+ARA	0.281

Table 11
Preterm Infant Complications

	Regimen			p-value*
	Control	DHA	DHA+ARA	
Retinopathy of Prematurity Test Results				
Absent	34 (76%)	44 (76%)	41 (79%)	0.91
I	8 (18%)	11 (19%)	6 (12%)	
II	2 (4%)	2 (3%)	4 (8%)	
III	1 (2%)	1 (2%)		
Present, but not graded			1 (2%)	
Ultrasound Examination for Intraventricular Hemorrhage				
None	47 (81%)	52 (84%)	49 (80%)	0.78
Stage 1	6 (10%)	9 (15%)	7 (11%)	
Stage 2	3 (5%)		2 (3%)	
Stage 3	1 (2%)		1 (2%)	
Stage 4	1 (2%)		2 (3%)	
Questionable		1 (2%)		
Posthemorrhagic Hydrocephalus developed?				
No	61 (98%)	65 (98%)	64 (97%)	1.00
Yes	1 (2%)	1 (2%)	2 (3%)	

*The statistical test was based on a dichotomous response: present or absent.

Table 12

Serious Adverse Events Reported During Study Formula Phase

Event	Regimen			p-value
	Control	DHA	DHA+ARA	
Any Event	4 (6%)	3 (5%)	4 (6%)	0.93
Other Respiratory Conditions of Fetus and Newborn	2 (3%)	0	0	0.10
Other Infection Specific to the Perinatal Period	1 (2%)	0	0	0.32
Intraventricular Hemorrhage	0	0	1 (2%)	1.00
Other Specified Perinatal Disorders of Digestive System	0	1 (2%)	0	1.00
Convulsions in Newborn	1 (2%)	0	0	0.32
Feeding Problems in Newborn	0	1 (2%)	1 (2%)	1.00
Hernia	0	0	1 (2%)	1.00
Other	0	1 (2%)	1 (2%)	1.00

Table 13

Serious Adverse Events Reported During the Term Formula Phase

	Regimen				
Event	Control	DHA	DHA + ARA	HM	p-value
Any Event	7 (13%)	9 (15%)	9 (15%)	1 (1%)	0.002 C vs D 0.79 C vs D+A 0.79 D vs D+A 1.00 C vs HM 0.006 D vs HM 0.001 D+A vs HM 0.001
Infectious Colitis, Enteritis, and Gastroenteritis	0	0	1 (2%)	0	0.67
Croup	0	0	1 (2%)	0	0.67
Bronchopneumonia, Organism Unspecified	2 (4%)	3 (5%)	6 (10%)	0	0.013 C vs D 1.00 C vs D+A 0.27 D vs D+A 0.49 C vs HM 0.15 D vs HM 0.064 D+A vs HM 0.004
Asthma, Unspecified	1 (2%)	0	0	0	0.21
Esophageal Reflux	0	1 (2%)	2 (3%)	0	0.23
Dyspepsia and Other Stomach Function Disorder	0	0	0	1 (1%)	1.0
Other Respiratory Conditions of Fetus and Newborn	1 (2%)	1 (2%)	3 (5%)	0	0.11
Convulsions	1 (2%)	0	0	0	0.21
Sudden Infant Death Syndrome	1 (2%)	1 (2%)	0	0	0.34
Hernia	2 (4%)	2 (3%)	0	0	0.11
Other	0	3 (5%)	2 (3%)	0	0.063

Appendix 1

Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_40	Wgt_48	Wgt_57
Male	Control	9698-0301	Weight (g)	1120	1240	1360	1590	1870					27.7			
			Age (weeks pca)	30.3	31.3	32.1	33.1	34.1								
Male	Control	9698-0304	Weight (g)	1450	1630	1940	2180						36.1	3731	5752	6816
			Age (weeks pca)	32.6	33.4	34.7	35.4							40.3	48.3	56.6
Male	Control	9699-0302	Weight (g)	958.0	1108	1251	1378	1659					23.9	3064	4993	6553
			Age (weeks pca)	30.7	31.7	32.7	33.7	34.7						39.9	48.0	57.9
Male	Control	9699-0306	Weight (g)	1185	1261	1437	1647	1933					26.9	3575	4936	6014
			Age (weeks pca)	31.0	32.0	33.0	34.0	35.0						40.3	48.3	57.1
Male	Control	9699-0308	Weight (g)	1600	1840	2752							43.3	3688	5504	6922
			Age (weeks pca)	34.4	35.4	38.3								40.3	48.3	57.3
Male	Control	9700-0301	Weight (g)	1810	1855	2075	2330	2595	3120				36.2	3745	5080	6610
			Age (weeks pca)	32.1	32.6	33.4	34.4	35.4	37.4					40.1	47.6	56.7
Male	Control	9701-0303	Weight (g)	1181	1298	1494	1785	2012					31.5	3070	3895	4965
			Age (weeks pca)	32.4	33.4	34.4	35.4	36.3						41.6	48.6	57.6
Male	Control	9701-0304	Weight (g)	1412	1566	1851	2117	2318					34.1	3070	5445	7135
			Age (weeks pca)	31.9	32.9	33.7	34.7	35.9						39.9	48.3	56.9
Male	Control	9702-0302	Weight (g)	1480	1775	2045	2240	2340	2570				33.8	3590	4840	6110
			Age (weeks pca)	31.0	32.1	33.0	34.0	34.6	35.6					40.1	48.6	58.4
Male	Control	9703-0302	Weight (g)	1785	2040	2375	2685	2955					41.7	3620	5850	7470
			Age (weeks pca)	33.3	34.6	35.6	36.4	37.4						39.7	48.6	57.3
Male	Control	9703-0304	Weight (g)	1475	1705	1920	2190	2425					34.2	3170	5240	6970
			Age (weeks pca)	31.7	33.0	34.0	34.9	35.7						40.1	47.7	57.1
Male	Control	9703-0308	Weight (g)	1140	1230	1445	1665	1945					28.9	2520	4010	5030
			Age (weeks pca)	31.7	32.6	33.7	34.7	35.7						39.7	48.4	56.9
Male	Control	9704-0303	Weight (g)	975.0	1205	1270	1450	1665	1760	2045			24.4	2150	3700	4950
			Age (weeks pca)	32.3	33.4	34.4	35.4	36.3	37.3	38.3				39.3	48.3	57.4

* Four subjects had more the 9 weights used in growth rate calculation. A complete listing appears on the last page.

Appendix 1

Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_40	Wgt_48	Wgt_57
Male	Control	9704-0305	Weight (g)	1315	1475	1640	1860						23.7			
			Age (weeks pca)	30.9	32.0	33.0	34.1									
Male	Control	9705-0302	Weight (g)	1280	1389	1588	1786	2240					30.9	2540	4936	5646
			Age (weeks pca)	33.0	34.0	35.0	36.0	37.4						39.6	47.4	56.4
Male	Control	9705-0304	Weight (g)	1270	1280	1570	1810						25.3	3291	5816	7490
			Age (weeks pca)	31.3	32.3	33.3	34.6							39.7	47.7	56.7
Male	Control	9706-0302	Weight (g)	1645	1865	2130	2435						37.1	2800	4660	6170
			Age (weeks pca)	35.7	36.6	37.7	38.7							40.1	48.7	56.7
Male	Control	9706-0303	Weight (g)	1875	1984	2135	2185	2465					22.2	3050	4550	6675
			Age (weeks pca)	33.7	34.7	35.6	36.4	37.3						41.0	48.6	56.9
Male	Control	9706-0308	Weight (g)	1655	1734	2005	2495						46.9	3835	5155	6090
			Age (weeks pca)	32.9	33.1	34.0	35.4							40.6	48.0	56.3
Male	Control	9707-0302	Weight (g)	1544	1820	2215	2450	2460					32.8	2930	3795	5185
			Age (weeks pca)	31.6	32.9	34.4	35.4	35.7						40.1	47.7	56.6
Male	Control	9707-0303	Weight (g)	1415	1600	1850	2195	2310					32.7	2530	4235	6530
			Age (weeks pca)	33.1	34.1	35.1	36.6	37.1						39.7	47.7	57.1
Male	Control	9707-0309	Weight (g)	1046	1442	1644	1910						30.7	2965	4465	
			Age (weeks pca)	30.9	32.7	33.7	34.9							39.9	48.0	
Male	Control	9708-0303	Weight (g)	1730	1960	2205	2520						37.4	3680	5470	7330
			Age (weeks pca)	32.7	33.7	34.7	35.7							40.1	48.1	57.0
Male	Control	9709-0302	Weight (g)	1090	1440	1660	1910	2040					30.8	3845	5700	6775
			Age (weeks pca)	29.9	31.7	32.7	33.7	34.3						39.9	48.0	56.7
Male	Control	9712-0301*	Weight (g)	1245	1221	1245	1291	1294	1330	1369	1402	1433	26.1			
			Age (weeks pca)	31.6	31.7	31.9	32.0	32.1	32.3	32.4	32.6	32.7				
Male	Control	9712-0302	Weight (g)	1292	1345	1456	1670	1835	1985				21.0	2160	3300	3980
			Age (weeks pca)	33.1	34.1	35.1	36.1	37.1	38.1					40.1	47.7	57.3

* Four subjects had more the 9 weights used in growth rate calculation. A complete listing appears on the last page.

Appendix 1

Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_40	Wgt_48	Wgt_57
Male	Control	9743-0301	Weight (g)	1520	1570	1670	1720						10.0	2260	4535	
			Age (weeks pca)	34.1	35.0	36.0	37.1							41.0	50.0	
Male	Control	9746-0301	Weight (g)	2065	2465	2760	3085	3085					48.9	3085	4795	6695
			Age (weeks pca)	37.6	38.9	39.7	40.6	40.6						40.6	47.6	57.6
Male	DHA	9698-0302	Weight (g)	1640	1860	3170							47.5	3170	5206	7036
			Age (weeks pca)	35.1	36.1	39.9								39.9	47.9	57.1
Male	DHA	9698-0306	Weight (g)	1620	1830	2090	2575						28.3	2575	4334	6022
			Age (weeks pca)	35.1	36.3	37.3	40.0							40.0	48.0	57.0
Male	DHA	9699-0301	Weight (g)	1018	1207	1360	1617						27.9	3121	5192	6752
			Age (weeks pca)	31.3	32.3	33.3	34.3							39.9	48.0	57.9
Male	DHA	9699-0303	Weight (g)	1258	1435	1631	1882	2724					48.3	2724	4341	5674
			Age (weeks pca)	32.4	33.4	34.4	35.4	36.4						40.1	48.1	57.0
Male	DHA	9699-0307	Weight (g)	1182	1358	1484	1666						22.5	1986	3206	4511
			Age (weeks pca)	34.7	35.7	36.7	37.7							40.0	48.0	57.0
Male	DHA	9700-0303	Weight (g)	1830	1980	2450	3045						45.4	3585	5420	7035
			Age (weeks pca)	33.9	34.4	35.9	37.7							39.6	47.4	56.7
Male	DHA	9701-0301	Weight (g)	1098	1234	1365	1689	1902	2019	2104	2276	2288	20.4	2805	3405	4660
			Age (weeks pca)	29.6	30.6	31.6	33.4	34.6	35.6	36.4	37.4	38.6		40.4	47.6	57.0
Male	DHA	9701-0305	Weight (g)	1621	1829	1880	2253	2582					34.7	3660		
			Age (weeks pca)	31.7	33.1	33.7	34.7	35.7						39.7		
Male	DHA	9703-0303	Weight (g)	1775	2030	2285	2595	2780					38.2	3080	3940	5260
			Age (weeks pca)	33.3	34.1	35.1	36.0	37.1						39.9	48.0	56.9
Male	DHA	9703-0306	Weight (g)	1725	1870	2180							41.7			
			Age (weeks pca)	33.4	34.0	35.0										
Male	DHA	9703-0307	Weight (g)	1525	1725	2020	2390						37.6	3120	4410	5600
			Age (weeks pca)	32.7	33.7	34.9	36.0							40.7	47.9	56.9

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Appendix 1

Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_40	Wgt_48	Wgt_57
Male	DHA	9704-0304	Weight (g)	1380	1570	1730	1960	2140					29.3	2880	3900	4300
			Age (weeks pca)	32.1	33.1	34.1	35.0	35.9						40.3	48.3	57.3
Male	DHA	9704-0306	Weight (g)	1320	1370	1550	1760	2020	2170				25.6		3750	4800
			Age (weeks pca)	30.7	31.7	32.7	33.7	34.7	35.9						48.0	57.0
Male	DHA	9705-0303	Weight (g)	1380	1446	1616	1843	2330					30.8	2370	4170	5787
			Age (weeks pca)	33.0	34.0	35.0	36.0	37.4						39.6	47.4	56.4
Male	DHA	9705-0305	Weight (g)	1490	1770	1980	2240						36.7	3291		
			Age (weeks pca)	31.1	32.1	33.1	34.0							39.6		
Male	DHA	9706-0304	Weight (g)	1490	1655	1915	2260						36.8	3335	5265	6900
			Age (weeks pca)	33.0	33.7	34.7	36.0							40.0	48.1	57.3
Male	DHA	9706-0306	Weight (g)	1604	1908	2160							42.8	3310	4205	5600
			Age (weeks pca)	34.4	35.4	36.3								41.4	47.6	56.9
Male	DHA	9707-0001	Weight (g)	1305	1429								17.7			
		—	Age (weeks pca)	31.0	32.0											
Male	DHA	9707-0304	Weight (g)	1555	1740	1990	2400	2570					36.9	3280	5115	6755
			Age (weeks pca)	32.0	33.0	34.0	35.4	36.0						39.9	48.0	57.6
Male	DHA	9707-0306	Weight (g)	1728	2040	2260	3050	3050					43.2	3050	5100	7150
			Age (weeks pca)	36.1	37.3	38.1	40.6	40.6						40.6	48.6	57.6
Male	DHA	9707-0307*	Weight (g)	1649	1675	1699	1732	1778	1811	1858	1882	1938	39.6			
			Age (weeks pca)	32.4	32.6	32.7	32.9	33.0	33.1	33.3	33.4	33.6				
Male	DHA	9707-1308	Weight (g)	1780	2045	3004	3004						36.7	3004	4420	6090
			Age (weeks pca)	34.4	35.7	39.3	39.3							39.3	47.3	57.7
Male	DHA	9707-2308	Weight (g)	1651	1923	2850	2850						35.8	2850	4375	5930
			Age (weeks pca)	34.4	35.7	39.3	39.3							39.3	47.3	57.7
Male	DHA	9708-0302	Weight (g)	1485	1740	2500							39.2	3873		6256
			Age (weeks pca)	33.3	34.3	37.0								42.9		57.3

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Appendix 1

Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_40	Wgt_48	Wgt_57
Male	DHA	9709-0301	Weight (g)	1490	1740	2000	2400	2800					44.4	3150	5080	6750
			Age (weeks pca)	32.4	33.4	34.4	35.4	36.7						39.4	47.4	56.4
Male	DHA	9709-0304	Weight (g)	1470	1520								7.1			
			Age (weeks pca)	34.4	35.4											
Male	DHA	9712-0304	Weight (g)	1545	1800	1985	2160	2550					30.5	3160	5200	7300
			Age (weeks pca)	33.0	34.0	35.0	36.0	37.6						40.3	48.1	57.1
Male	DHA	9712-0306	Weight (g)	1240	1435	1695	1945						33.9	3040	4680	5860
			Age (weeks pca)	31.5	32.5	33.5	34.5							39.6	48.6	57.6
Male	DHA	9743-0303	Weight (g)	1700	1810	2100	2300						31.1	3100	5500	
			Age (weeks pca)	32.9	33.9	34.9	35.7							40.6	48.6	
Male	DHA	9743-0304	Weight (g)	1530	1880	2160	2375	2440					32.2	3628	5840	
			Age (weeks pca)	32.3	34.0	35.0	36.0	36.4						38.1	50.6	
Male	DHA+ARA	9698-0305	Weight (g)	1120	1340	1550							20.9	2440	5525	6646
			Age (weeks pca)	30.7	32.6	33.6								37.4	47.6	56.6
Male	DHA+ARA	9698-0308	Weight (g)	1410	1690	1870	2120						32.0	3553	6007	7937
			Age (weeks pca)	31.1	32.4	33.3	34.3							40.3	47.6	57.3
Male	DHA+ARA	9699-0304	Weight (g)	1499	1689	1950	2355						29.8	2355	3404	4993
			Age (weeks pca)	36.1	37.1	38.1	40.3							40.3	48.0	57.1
Male	DHA+ARA	9699-0305	Weight (g)	1056	1134	1290	1490						17.2	2610	4256	5050
			Age (weeks pca)	32.0	33.0	34.0	35.7							40.6	48.7	57.6
Male	DHA+ARA	9700-0302	Weight (g)	1635	1880	2235	2570	2735					40.7	3255	5540	7380
			Age (weeks pca)	33.9	34.7	35.9	36.9	37.9						39.7	47.7	56.7
Male	DHA+ARA	9701-0302	Weight (g)	1442	1686	2045	2835						48.9	3240	5055	6600
			Age (weeks pca)	33.6	34.6	35.6	37.7							39.7	46.7	56.7
Male	DHA+ARA	9701-0306	Weight (g)	1587	2037	2245	2460	2756	3072	3228			41.4	3960	5200	
			Age (weeks pca)	32.3	33.4	34.4	35.3	36.3	37.3	37.7				42.3	48.4	

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Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_40	Wgt_48	Wgt_56
Male	DHA+ARA	9701-0307	Weight (g)	1397	1710	1919	2932						42.5	3445	5930	7475
			Age (weeks pca)	33.3	34.3	35.1	38.4							40.6	48.6	57.4
Male	DHA+ARA	9702-0301	Weight (g)	1670	1865	2160	2660						36.0	3780	5250	
			Age (weeks pca)	32.0	33.0	34.0	36.0							40.6	47.6	
Male	DHA+ARA	9702-0303	Weight (g)	1650	1905	2660							40.7	3500	5160	6520
			Age (weeks pca)	32.9	33.9	36.4								40.0	48.0	56.4
Male	DHA+ARA	9703-0301	Weight (g)	1255	1460	1745	2055	2415					42.3	4350	6020	6720
			Age (weeks pca)	29.4	30.4	31.3	32.3	33.4						40.4	47.4	56.6
Male	DHA+ARA	9703-0305	Weight (g)	1440	1635	1830	2115	2390	2590				34.1	3170	4330	5630
			Age (weeks pca)	32.0	33.0	34.0	35.0	36.1	36.9					40.0	47.9	56.7
Male	DHA+ARA	9704-0301	Weight (g)	1110	1270	1490	1740	2050					35.1	3220	5460	7050
			Age (weeks pca)	30.6	31.6	32.4	33.4	34.4						39.9	47.7	56.7
Male	DHA+ARA	9704-0302	Weight (g)	1080	1230	1370	1520	1680	1840				22.2	2570	6540	8050
			Age (weeks pca)	32.0	33.0	34.0	34.9	36.0	36.9					40.0	48.1	57.4
Male	DHA+ARA	9705-0301	Weight (g)	1300	1440	1620	1870						27.0	2979	4400	5873
			Age (weeks pca)	32.7	33.7	34.7	35.7							40.1	48.1	58.0
Male	DHA+ARA	9705-0306	Weight (g)	1320	1490	1700	2020	2300					32.7	3631	5447	6809
			Age (weeks pca)	31.4	32.4	33.4	34.4	35.9						39.9	47.9	56.9
Male	DHA+ARA	9705-0307	Weight (g)	1480	1650	1810	2240						36.4	3007	5589	6596
			Age (weeks pca)	34.4	35.4	36.1	37.4							39.9	48.4	56.7
Male	DHA+ARA	9706-0305	Weight (g)	1330	1455	1660	1930						31.4	2695	4820	6225
			Age (weeks pca)	33.9	34.4	35.4	36.6							39.9	48.1	58.1
Male	DHA+ARA	9706-0307	Weight (g)	1355	1585	1825	2270						40.0	3585	5955	6925
			Age (weeks pca)	31.9	33.0	33.9	35.1							40.4	49.1	57.6
Male	DHA+ARA	9706-0309	Weight (g)	1620	1910	2150							40.3	3460	5255	5775
			Age (weeks pca)	34.1	35.3	36.0								40.9	48.7	57.4

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Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_40	Wgt_48	Wgt_57
Male	DHA+ARA	9707-0301	Weight (g)	1553	1980	2280	2720						41.5	3395	4950	6285
			Age (weeks pca)	32.6	34.3	35.3	36.6							40.1	47.9	56.9
Male	DHA+ARA	9707-0305	Weight (g)	1755	1990	2245	2505	2770					37.4			
			Age (weeks pca)	33.9	34.7	35.7	36.7	37.7								
Male	DHA+ARA	9707-0310	Weight (g)	1620	1828	2140	3195						44.8	3585	5170	6725
			Age (weeks pca)	32.7	33.7	34.7	37.9							39.7	47.9	56.3
Male	DHA+ARA	9708-0301	Weight (g)	1640	1880	2200	2420						38.0	3730	4835	6185
			Age (weeks pca)	32.7	33.7	34.7	35.7							40.1	47.9	57.0
Male	DHA+ARA	9708-0304	Weight (g)	1680	2180								55.6			
			Age (weeks pca)	34.6	35.9											
Male	DHA+ARA	9709-0303	Weight (g)	1470	1810								48.6			
			Age (weeks pca)	32.6	33.6											
Male	DHA+ARA	9709-0305	Weight (g)	1410	1655	1900	2160						35.6	2630	4570	5520
			Age (weeks pca)	34.4	35.4	36.4	37.4							39.7	47.7	57.1
Male	DHA+ARA	9712-0303	Weight (g)	1180	1210	1450	1590						20.9	2520	3500	5010
			Age (weeks pca)	31.4	32.3	33.4	34.4							40.4	47.4	56.4
Male	DHA+ARA	9712-0305	Weight (g)	1325	1505	1785	2010	2300					34.1	3030	4350	5510
			Age (weeks pca)	31.5	32.5	33.5	34.5	35.6						39.6	48.6	57.6
Male	DHA+ARA	9723-0301	Weight (g)	1630	1728	1961	2214						28.4	3104		5986
			Age (weeks pca)	33.9	34.9	35.9	36.9							40.3		58.9
Male	HM	9698-0601												3518	5497	6582
														40.0	48.3	56.9
Male	HM	9698-0602												3177	5220	6355
														40.0	48.1	57.0
Male	HM	9698-0603												3858	5447	6454
														40.0	48.0	57.0

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Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_40	Wgt_48	Wgt_57
Male	HM	9698-0604												4355	5092	6383
														40.0	48.0	57.0
Male	HM	9698-0605												3433	4979	6426
														40.0	48.1	57.1
Male	HM	9699-0501												3915	6639	7773
														40.0	48.3	57.4
Male	HM	9699-0502												3802	5787	7178
														40.0	48.4	57.4
Male	HM	9701-0601												3317	5555	7070
														40.0	47.9	56.4
Male	HM	9701-0602												3487	5833	8070
														40.0	47.3	58.3
Male	HM	9701-0603												3232	4940	5855
														40.0	47.4	56.4
Male	HM	9701-0604												3600	5215	6285
														40.0	47.9	56.9
Male	HM	9701-0605												3402	5575	7210
														40.0	47.6	57.6
Male	HM	9701-0606												3090	4485	5445
														40.0	47.7	56.7
Male	HM	9702-0601												3480	5780	6530
														40.0	48.6	56.6
Male	HM	9702-0602												3165	5060	6660
														40.0	48.3	57.1
Male	HM	9703-0502												2670	5420	7220
														40.0	48.3	57.1

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Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_40	Wgt_48	Wgt_57
Male	HM	9703-0503												4100	6740	8330
														40.0	47.4	56.4
Male	HM	9703-0504												3435	6000	7930
														40.0	48.1	57.1
Male	HM	9704-0502												3285	5220	6560
														40.0	48.1	56.6
Male	HM	9704-0503												3400	5200	6725
														40.0	48.7	56.9
Male	HM	9705-0601												3200	5617	6752
														40.0	48.3	57.3
Male	HM	9705-0602												3860	6227	
														40.0	48.0	
Male	HM	9706-0601												3152	5105	6545
														40.0	49.0	57.0
Male	HM	9706-0602												3557	5175	7315
														40.0	47.4	57.7
Male	HM	9706-0603												3192	5070	6970
														40.0	47.9	56.7
Male	HM	9706-0604												3461	4225	5525
														40.0	48.0	57.1
Male	HM	9706-0605												3870	6220	7660
														40.0	48.1	56.4
Male	HM	9706-0606												4315	5975	6720
														40.0	48.3	56.6
Male	HM	9707-0601												3263	4730	5825
														40.0	48.1	57.0

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Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_40	Wgt_48	Wgt_57
Male	HM	9707-0602												3206	4515	6220
														40.0	48.1	57.7
Male	HM	9707-0603												4256	6930	8810
														40.0	48.0	57.0
Male	HM	9707-0604												3419	5460	6130
														40.0	48.0	56.7
Male	HM	9707-0605												3433		
														40.0		
Male	HM	9707-0606												3603	5825	
														40.0	48.4	
Male	HM	9707-0607												3569	5410	6870
														40.0	47.9	56.9
Male	HM	9707-0608												3348	5135	6370
														40.0	48.0	57.0
Male	HM	9707-0609												3348		
														40.0		
Male	HM	9708-0601												3064	5220	6595
														40.0	47.6	56.4
Male	HM	9708-0602												4085		
														40.0		
Male	HM	9708-0603												3319	5135	6327
														40.0	48.4	57.1
Male	HM	9708-0604												3291		
														40.0		
Male	HM	9708-0605												3796		
														40.0		

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Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_40	Wgt_48	Wgt_57
Male	HM	9708-0606												4020 40.0	4645 48.4	5405 57.1
Male	HM	9708-0607												3333 40.0	4043 47.9	5180 56.7
Male	HM	9709-0505												3400 40.0		
Female	Control	9698-0003*	Weight (g) Age (weeks pca)	1020 31.1	1050 31.3	1070 31.4	1080 31.6	1080 31.7	1060 31.9	1080 32.0	1070 32.1		5.6			
Female	Control	9699-0001	Weight (g) Age (weeks pca)	1464 32.7	1672 33.7	1862 34.7	2000 35.7	2145 36.7					24.1	2610 39.7	4369 47.9	5220 56.9
Female	Control	9699-0003	Weight (g) Age (weeks pca)	1473 34.0	1629 35.0	1860 36.0	2497 38.0						37.3	2780 40.0	4596 48.0	5816 57.0
Female	Control	9701-0003	Weight (g) Age (weeks pca)	1480 34.6	1633 35.6	1903 36.6	1975 37.3	2292 38.6					29.1	2675 40.6	4165 48.6	5200 55.6
Female	Control	9701-0005	Weight (g) Age (weeks pca)	1174 30.7	1366 31.7	1555 32.7	1745 33.7	1976 34.7					28.3	3175 39.7	5140 48.4	6280 56.4
Female	Control	9701-0008	Weight (g) Age (weeks pca)	1391 34.3	1569 35.3	1898 36.4	2198 37.3	2406 37.9					41.1	2980 40.4	4425 47.4	5815 56.4
Female	Control	9701-0011	Weight (g) Age (weeks pca)	1050 30.6	1254 31.4	1492 32.4	1756 33.4	2044 34.4					36.6	2870 39.7	4420 48.6	5505 57.4
Female	Control	9702-0002	Weight (g) Age (weeks pca)	1222 31.7	1371 32.7	1570 34.1	1750 35.1	1995 36.0	2390 37.1				29.4	3380 40.4	4900 47.6	
Female	Control	9702-0004	Weight (g) Age (weeks pca)	1454 31.0	1555 31.9	1840 33.1	2530 36.0						31.6	3600 39.9	5160 47.7	6900 56.7
Female	Control	9702-0010	Weight (g) Age (weeks pca)	1775 34.0	2065 35.0	2410 36.0	2645 37.0						42.2	3060 39.9	4820 48.3	6690 57.6

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Appendix 1

Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_40	Wgt_48	Wgt_57
Female	Control	9703-0002	Weight (g)	1170	1250	1390	1570	1825	2130				26.4	3210	4750	
			Age (weeks pca)	29.1	30.4	31.3	32.4	33.4	34.3					39.6	47.4	
Female	Control	9703-0005	Weight (g)	1420	1590	1765	1900	2220					29.5	2610	4330	5640
			Age (weeks pca)	31.4	32.3	33.3	33.9	35.3						37.3	46.0	55.0
Female	Control	9703-0008	Weight (g)	1495	1715	2095	2445	2685					48.3	3360	4780	6410
			Age (weeks pca)	33.0	34.0	35.0	36.0	36.6						40.1	47.7	56.1
Female	Control	9705-0004	Weight (g)	1120	1290	1490	1660						28.3	2722	4085	5646
			Age (weeks pca)	31.3	32.3	33.3	34.0							39.7	46.6	55.0
Female	Control	9706-0003	Weight (g)	1515	1673	1965	2330						37.9			
			Age (weeks pca)	35.1	36.3	37.1	38.3									
Female	Control	9706-0005	Weight (g)	1485	1610	1805	2150						31.7	2740	4165	5305
			Age (weeks pca)	33.0	33.7	34.7	36.0							40.0	48.1	57.3
Female	Control	9706-0009	Weight (g)	1525	1620	1960							31.6	3640	5495	7225
			Age (weeks pca)	32.3	32.9	34.3								40.3	47.6	53.4
Female	Control	9706-0010	Weight (g)	1905	2185								56.0	3655	5390	6535
			Age (weeks pca)	34.3	35.0									40.0	48.4	56.7
Female	Control	9706-0013	Weight (g)	1185	1270	1585	1810						31.1	2680	3800	
			Age (weeks pca)	31.6	32.4	33.6	34.6							40.1	48.4	
Female	Control	9706-0016	Weight (g)	1510	1765	1935							32.6	3320	4535	5297
			Age (weeks pca)	32.0	33.1	33.9								40.7	48.7	56.6
Female	Control	9707-0003	Weight (g)	1465	1505	1655	2010	2325	2765				30.2	3110	4125	4995
			Age (weeks pca)	32.0	32.6	33.6	35.3	36.4	38.3					40.1	48.1	57.1
Female	Control	9707-0006	Weight (g)	1866	3430	3430							41.2	3430	5385	7250
			Age (weeks pca)	34.6	40.0	40.0								40.0	48.9	57.3
Female	Control	9707-1006	Weight (g)	1815	3330	3330							39.9	3330	5490	6920
			Age (weeks pca)	34.6	40.0	40.0								40.0	48.9	57.3

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Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_40	Wgt_48	Wgt_57
Female	Control	9708-0001	Weight (g)	1410	1600	1850	2050						27.2	2910	4734	
			Age (weeks pca)	33.4	34.4	35.4	36.9							40.6	48.4	
Female	Control	9708-0003	Weight (g)	940.0	970.0								4.3			
			Age (weeks pca)	30.0	31.0											
Female	Control	9708-0008	Weight (g)	1380	1605	1860	2180						33.1	2582	4110	5361
			Age (weeks pca)	32.9	33.7	34.9	36.3							39.3	47.4	57.1
Female	Control	9709-0002	Weight (g)	1980	2225	2400							30.0			
			Age (weeks pca)	32.7	33.7	34.7										
Female	Control	9709-0005	Weight (g)	1175	1425	1665	1945	2200					32.3	2975	4700	5900
			Age (weeks pca)	31.9	33.3	34.6	35.6	36.3						39.6	48.4	56.7
Female	Control	9712-0005	Weight (g)	972.0	1145	1290	1490	1695					25.6	2930	4450	5880
			Age (weeks pca)	29.1	30.1	31.1	32.1	33.1						40.3	47.6	57.1
Female	Control	9712-0006	Weight (g)	1203	1358	1585	1790						28.4	3030	4560	6230
			Age (weeks pca)	31.9	32.9	33.9	34.9							39.7	48.0	57.0
Female	Control	9743-0003	Weight (g)	1300	1520	1740	1890						24.0		4000	5160
			Age (weeks pca)	31.6	33.4	34.1	35.1								48.4	57.4
Female	Control	9746-0001	Weight (g)	1420	1740	2075	2320	2625					42.7	3170	4145	5192
			Age (weeks pca)	32.6	33.6	34.6	35.6	36.6						39.7	47.6	56.6
Female	DHA	9698-0004	Weight (g)	1410	1650	1890	2140						34.7	3787	4795	6291
			Age (weeks pca)	30.1	31.1	32.1	33.1							40.0	48.0	57.0
Female	DHA	9698-0006	Weight (g)	1110	1240	1420	1720						28.7			
			Age (weeks pca)	30.7	31.7	32.7	33.7									
Female	DHA	9698-0009	Weight (g)	1205	1310	1520	1630	2020					25.9	2891	3979	5121
			Age (weeks pca)	30.3	31.4	32.4	33.1	34.9						40.0	48.0	57.0
Female	DHA	9698-0307	Weight (g)	1790	2110	2450							29.7	3135	5185	6695
			Age (weeks pca)	34.4	35.7	37.6								39.4	47.4	56.4

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Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_40	Wgt_48	Wgt_57
Female	DHA	9699-0002	Weight (g)	1313	1477	1669	1929	2380					36.9	3177	5787	7093
			Age (weeks pca)	32.9	33.9	34.9	35.9	36.9						39.7	47.7	56.7
Female	DHA	9700-0001	Weight (g)	1580	1820	2050	2295	2500					34.5	3210	5110	6300
			Age (weeks pca)	32.4	33.4	34.3	35.3	36.3						40.1	48.1	57.1
Female	DHA	9701-0001	Weight (g)	1300	1356	1586	1924	2125					34.2	2910	4325	5625
			Age (weeks pca)	33.0	34.0	35.0	36.0	36.6						39.6	48.0	57.0
Female	DHA	9701-0004	Weight (g)	1108	1261	1441	1671	1897					28.4	3020	4855	6040
			Age (weeks pca)	30.7	31.7	32.7	33.7	34.7						39.7	48.4	56.4
Female	DHA	9701-0012	Weight (g)	1674	1928	2151	2311	2685	2685				30.1	2685		
			Age (weeks pca)	34.9	35.9	36.9	37.6	39.6	39.6					39.6		
Female	DHA	9701-0014	Weight (g)	1422	1631	1858	2455						37.2	2970	4605	5140
			Age (weeks pca)	33.9	34.9	35.9	37.9							39.9	47.7	56.9
Female	DHA	9702-0001	Weight (g)	1780	2115	2390	3000						35.8	3850	5610	6600
			Age (weeks pca)	31.6	32.9	33.9	36.4							40.0	49.6	57.0
Female	DHA	9702-0006	Weight (g)	1850	2005	2650	2650						27.3	2650	4450	6020
			Age (weeks pca)	35.4	36.1	39.6	39.6							39.6	48.4	56.4
Female	DHA	9702-0007	Weight (g)	1285	1459	1780	1965	2035					29.6			
			Age (weeks pca)	31.1	32.1	33.6	34.4	34.9								
Female	DHA	9702-0008	Weight (g)	1605	1930	3540	3540						51.3	3540	5920	7820
			Age (weeks pca)	34.1	35.1	39.6	39.6							39.6	47.6	57.1
Female	DHA	9703-0003	Weight (g)	1255	1355	1535	1845	2150					34.8	2430	4130	5010
			Age (weeks pca)	34.4	35.1	36.1	37.1	38.1						39.4	48.0	56.1
Female	DHA	9703-0004	Weight (g)	1170	1340	1550	1795	2225					33.9	2870	4610	6490
			Age (weeks pca)	32.6	33.3	34.3	35.3	37.0						39.4	48.1	57.1
Female	DHA	9703-0009	Weight (g)	1570	1830	2095	2395	2655					34.6	3160	4480	5570
			Age (weeks pca)	33.3	34.3	35.1	36.3	37.9						40.4	48.4	58.0

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Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_40	Wgt_48	Wgt_57
Female	DHA	9704-0004	Weight (g)	1440	1670	1740							30.5	3100	5830	8630
			Age (weeks pca)	33.6	34.6	35.0								40.0	48.0	57.0
Female	DHA	9704-0005	Weight (g)	1050	1310	1490	1700	1890					30.0	3360	4860	6100
			Age (weeks pca)	29.7	30.9	31.7	32.7	33.7						39.6	48.0	57.0
Female	DHA	9705-0001	Weight (g)	1220	1370	1590	1880	2098					31.9	3092	4795	5986
			Age (weeks pca)	32.7	33.6	34.7	35.7	36.7						40.1	48.1	57.1
Female	DHA	9706-0006	Weight (g)	1270	1405	1630	1930						31.7	2705	4145	5320
			Age (weeks pca)	33.0	33.7	34.7	36.0							40.0	48.1	57.3
Female	DHA	9706-0008	Weight (g)	990.0	1188	1345	1485						23.0	2120		
			Age (weeks pca)	33.4	34.6	35.7	36.4							39.9		
Female	DHA	9706-0012	Weight (g)	1610	1830	2130	2280						32.5	3530	4790	
			Age (weeks pca)	31.6	32.4	33.6	34.6							40.1	48.4	
Female	DHA	9706-0014	Weight (g)	1080	1170	1395	1560	1804					26.2	3295	5600	7675
			Age (weeks pca)	31.3	32.6	33.4	34.4	35.3						40.6	49.4	58.0
Female	DHA	9707-0004	Weight (g)	1635	1771	2850							38.1	3045	4595	5765
			Age (weeks pca)	34.0	35.0	38.7								40.0	48.0	57.0
Female	DHA	9707-0308	Weight (g)	2005	3440	3440							42.2	3440	4800	6360
			Age (weeks pca)	34.4	39.3	39.3								39.3	47.3	57.7
Female	DHA	9708-0004	Weight (g)	1460	1665	1955	2280	2485					38.1			
			Age (weeks pca)	32.6	33.6	34.6	35.6	36.6								
Female	DHA	9708-0006	Weight (g)	1485	1775	2110	2380						39.5	3010	4620	6530
			Age (weeks pca)	33.7	34.7	35.7	37.0							40.1	48.1	57.0
Female	DHA	9709-0001	Weight (g)	1250	1490	1755	1970	2250	2520				33.8	3500		
			Age (weeks pca)	29.6	31.0	32.0	33.0	34.0	35.0					40.1		
Female	DHA	9709-0003	Weight (g)	1540	1725	2015	2155						30.5	2580	4080	5420
			Age (weeks pca)	34.4	35.4	36.4	37.4							40.3	47.7	57.1

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Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_40	Wgt_48	Wgt_57
Female	DHA	9712-0001	Weight (g)	987.0	1120	1270	1470	1685					24.9	2940	3980	5250
			Age (weeks pca)	30.0	31.0	32.0	33.0	34.0						40.1	48.1	57.1
Female	DHA	9712-0002	Weight (g)	1060	1230	1430							26.4			
			Age (weeks pca)	32.7	33.7	34.7										
Female	DHA	9712-0007	Weight (g)	1082	1230	1440	1650						27.3	2425	4250	5340
			Age (weeks pca)	32.7	33.7	34.7	35.7							39.7	47.9	56.9
Female	DHA	9743-0001	Weight (g)	1000	1170	1470	1800	1930					33.5		4140	5400
			Age (weeks pca)	32.1	33.1	34.4	35.7	36.1							48.3	57.3
Female	DHA	9743-0002	Weight (g)	1380	1570	1845	1975						29.7		4540	5160
			Age (weeks pca)	32.1	33.3	34.1	35.1								48.4	57.4
Female	DHA+ARA	9698-0001	Weight (g)	1550	1690	2000	2380						37.1	3530	5348	6582
			Age (weeks pca)	31.6	32.6	33.6	34.9							40.0	47.7	56.7
Female	DHA+ARA	9698-0002	Weight (g)	1580	1870	2130	2260						31.8	3241		
			Age (weeks pca)	32.6	33.7	34.6	35.7							40.7		
Female	DHA+ARA	9699-0004	Weight (g)	985.0	1122	1283	1536	1788					28.9	3177	5107	6979
			Age (weeks pca)	31.0	32.0	33.0	34.0	35.0						41.3	48.3	57.3
Female	DHA+ARA	9699-0005	Weight (g)	1330	1542	1688	2000	2330					35.1	4029	6752	8341
			Age (weeks pca)	31.9	32.9	33.9	34.9	35.9						40.0	48.0	57.0
Female	DHA+ARA	9700-0002	Weight (g)	1315	1525	1885	2035	2220	2480				31.9	3340	4930	6420
			Age (weeks pca)	30.3	31.3	32.3	33.3	34.1	35.6					40.3	48.1	57.1
Female	DHA+ARA	9701-0002	Weight (g)	1398	1609	1887	2210	2420					37.8	2930	5115	6525
			Age (weeks pca)	33.4	34.4	35.4	36.4	37.4						39.4	48.4	56.4
Female	DHA+ARA	9701-0006	Weight (g)	1720	1859	2113	2456	2728					38.3	3600	5045	6270
			Age (weeks pca)	32.3	33.3	34.3	35.3	36.1						40.3	48.0	57.3
Female	DHA+ARA	9701-0007	Weight (g)	1469	1427	1590	1982	2227					29.8	2680	4935	6955
			Age (weeks pca)	33.7	34.9	35.7	36.7	37.7						39.9	47.9	56.9

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Female	DHA+ARA	9701-0010	Weight (g)	1488	1703	1978	2234	2433	2759				34.6	3500	5545	
			Age (weeks pca)	32.3	33.4	34.4	35.3	36.1	37.7					41.1	48.4	
Female	DHA+ARA	9701-0013	Weight (g)	1841	2019								35.6		4545	5550
			Age (weeks pca)	33.0	33.7										48.7	57.4
Female	DHA+ARA	9702-0003	Weight (g)	1293	1488	1820	2155	2400					39.9	4190	6220	7500
			Age (weeks pca)	30.1	31.1	32.1	33.4	34.1						40.0	48.4	56.9
Female	DHA+ARA	9702-0005	Weight (g)	1895	2060	2300	2525	2710					29.9	3025	4300	5340
			Age (weeks pca)	34.0	35.0	36.0	37.0	38.0						40.0	47.4	56.4
Female	DHA+ARA	9702-0009	Weight (g)	1725	2000	2230	2595	2655					40.9	2905	4680	6410
			Age (weeks pca)	34.0	35.0	36.0	37.0	37.3						39.9	48.3	57.6
Female	DHA+ARA	9703-0001	Weight (g)	1145	1255	1450	1680	1955					28.9	3030	4250	5420
			Age (weeks pca)	31.3	32.1	33.1	34.3	35.3						41.0	48.1	57.3
Female	DHA+ARA	9703-0006	Weight (g)	1865	2200	2560	2880						49.1	3600	5400	6650
			Age (weeks pca)	34.0	35.0	35.9	37.0							40.0	48.1	56.7
Female	DHA+ARA	9703-0007	Weight (g)	1390	1495	1620	1880	2030	2240				27.4	2850	4190	5850
			Age (weeks pca)	32.0	33.1	34.0	35.0	35.7	36.6					40.0	47.9	56.7
Female	DHA+ARA	9704-0002	Weight (g)	960.0	1090	1200	1370	1570	1780	2070			26.7	3110	5150	6800
			Age (weeks pca)	29.0	30.0	30.9	31.9	32.9	33.9	34.9				40.0	48.0	57.3
Female	DHA+ARA	9704-0003	Weight (g)	1690	1840								30.0	4000	5400	6640
			Age (weeks pca)	32.7	33.4									40.0	48.0	57.0
Female	DHA+ARA	9705-0003	Weight (g)	1760	2260	2500	2920						49.8	3376	5107	6894
			Age (weeks pca)	34.4	35.7	36.6	37.7							39.9	48.4	56.9
Female	DHA+ARA	9705-0005*	Weight (g)	1075	1120	1185	1280	1310	1310	1265	1350	1380	22.1	2600	4000	5050
			Age (weeks pca)	31.1	31.4	31.7	32.1	32.4	32.7	33.0	33.3	33.4		40.4	48.0	57.0
Female	DHA+ARA	9706-0001	Weight (g)	1290	1515	1685	2060						34.5	4100	6550	7655
			Age (weeks pca)	31.7	32.9	33.7	34.9							40.1	48.6	56.7

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Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_40	Wgt_48	Wgt_57
Female	DHA+ARA	9706-0002	Weight (g)	1395	1710	1884	2275						34.8	2845	4645	5550
			Age (weeks pca)	31.9	33.0	33.9	35.4							40.3	48.9	57.3
Female	DHA+ARA	9706-0004	Weight (g)	1550	1705	2050							36.1	2645	4225	4935
			Age (weeks pca)	36.7	37.6	38.7								41.7	49.7	58.0
Female	DHA+ARA	9706-0007	Weight (g)	1235	1490	1820	1930						34.3	2505		
			Age (weeks pca)	33.4	34.6	35.7	36.4							40.3		
Female	DHA+ARA	9706-0011	Weight (g)	1900	2105								41.0	3430	5175	6140
			Age (weeks pca)	34.3	35.0									40.0	48.4	56.7
Female	DHA+ARA	9706-0015	Weight (g)	1670	1975	2210							41.6	3005	4465	5810
			Age (weeks pca)	34.6	35.6	36.4								40.9	48.4	57.6
Female	DHA+ARA	9706-0017	Weight (g)	1465	1700	1895	2170						33.4			
			Age (weeks pca)	32.3	33.4	34.3	35.3									
Female	DHA+ARA	9707-0002	Weight (g)	1775	2240	2385	2610						33.2			
			Age (weeks pca)	34.3	36.0	36.9	37.9									
Female	DHA+ARA	9708-0002	Weight (g)	1535	1700	1980	2200						32.5	2724	4645	6315
			Age (weeks pca)	33.0	34.0	35.0	36.0							38.1	47.6	55.4
Female	DHA+ARA	9708-0005	Weight (g)	1125	1345	1610	1980						40.4	3121	5855	7875
			Age (weeks pca)	32.4	33.4	34.4	35.4							39.4	47.4	57.4
Female	DHA+ARA	9708-0007	Weight (g)	1200	1440	1680	1975						36.6			
			Age (weeks pca)	31.3	32.3	33.3	34.3									
Female	DHA+ARA	9709-0004	Weight (g)	1350	1560	1885	2250	2475					37.0	3295	5250	6685
			Age (weeks pca)	31.9	33.3	34.6	35.6	36.3						39.7	48.4	56.7
Female	DHA+ARA	9712-0003	Weight (g)	1283	1410	1590	1850	2010					27.1	2580	4130	5640
			Age (weeks pca)	32.0	33.0	34.0	35.0	36.0						40.0	48.2	57.5
Female	DHA+ARA	9712-0004	Weight (g)	1575	1780	1890	2080	2530					29.7	3220	4920	6600
			Age (weeks pca)	33.0	34.0	34.6	35.6	37.6						40.3	48.1	57.1

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Appendix 1

Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_40	Wgt_48	Wgt_57
Female	DHA+ARA	9712-0008	Weight (g)	1590	1780	1990	2475						37.2	2960	4470	5760
			Age (weeks pca)	34.0	35.0	35.8	37.4							40.1	48.1	57.1
Female	DHA+ARA	9746-0002	Weight (g)	1249	1429	1597	1814	2110					30.1	2680	4010	5362
			Age (weeks pca)	32.7	33.7	34.7	35.7	36.7						39.9	46.9	56.9
Female	HM	9698-0501												3546	4880	
														40.0	48.3	
Female	HM	9698-0502												3518	5972	
														40.0	47.9	
Female	HM	9698-0503												3390	4213	5319
														40.0	48.3	57.1
Female	HM	9698-0504												3383	5234	6667
														40.0	48.7	57.9
Female	HM	9698-0505												3646	4638	5653
														40.0	48.3	57.0
Female	HM	9699-0601												2582	4766	5731
														40.0	49.0	57.0
Female	HM	9699-0602												4284	4823	5986
														40.0	48.0	57.0
Female	HM	9699-0603												3716	4482	5674
														40.0	47.7	56.7
Female	HM	9699-0604												3660	4738	6355
														40.0	48.0	57.0
Female	HM	9699-0605												3433	5617	7603
														40.0	48.4	57.6
Female	HM	9701-0501												3884	5630	6450
														40.0	47.7	57.7

* Four subjects had more the 9 weights used in growth rate calculation. A complete listing appears on the last page.

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Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_40	Wgt_48	Wgt_57
Female	HM	9701-0502												3858	5420	6700
														40.0	48.6	57.6
Female	HM	9701-0503												3430	4265	5085
														40.0	47.4	57.4
Female	HM	9701-0504												3317	5020	6230
														40.0	48.1	57.1
Female	HM	9702-0501												3302	5540	6630
														40.0	47.7	56.7
Female	HM	9702-0502												2658	5310	6800
														40.0	47.4	57.1
Female	HM	9702-0503												2895	3430	4530
														40.0	47.7	57.4
Female	HM	9702-0504												3401	5390	6270
														40.0	48.0	57.4
Female	HM	9702-0505												3141	4210	5320
														40.0	47.9	57.0
Female	HM	9702-0506												3762	6040	7600
														40.0	48.9	57.7
Female	HM	9702-0507												2718	4050	4940
														40.0	48.9	57.4
Female	HM	9702-0508												2927	4240	5860
														40.0	47.4	57.0
Female	HM	9703-0501												4085	5260	6360
														40.0	48.1	57.1
Female	HM	9703-0505												3390	5760	7670
														40.0	48.3	57.3

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Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_40	Wgt_48	Wgt_57
Female	HM	9703-0506												3405 40.0	6170 47.9	7490 56.9
Female	HM	9703-0507												3085 40.0	5090 48.0	6550 56.3
Female	HM	9704-0501												3194 40.0	4700 48.1	5880 57.4
Female	HM	9705-0501												3120 40.0	4500 48.1	5702 57.1
Female	HM	9705-0502												4080 40.0	6327 48.3	7348 57.3
Female	HM	9706-0501												3396 40.0	5000 48.3	6645 58.1
Female	HM	9706-0502												3041 40.0	4315 47.7	5525 57.6
Female	HM	9707-0501												4653 40.0	5515 47.9	6770 56.6
Female	HM	9707-0502												3419 40.0	5500 48.0	7080 57.1
Female	HM	9707-0503												3773 40.0	5785 47.9	7675 56.9
Female	HM	9707-0505												3716 40.0		
Female	HM	9708-0501												3688 40.0	5440 48.1	6890 57.6
Female	HM	9708-0502												3454 40.0	5192 48.1	5950 57.4

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Listing of Weights Included in the Statistical Analyses

Gender	Regimen	Subject	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Growth Rate g/day	Wgt_40	Wgt_48	Wgt_57
Female	HM	9708-0503												2977 40.0	5165 48.1	7040 57.4
Female	HM	9708-0504												3864 40.0	5660 48.4	6705 57.4
Female	HM	9708-0505												3831 40.0	5800 47.7	7435 57.6
Female	HM	9709-0501												3550 40.0		
Female	HM	9709-0502												3715 40.0	5205 48.0	6100 56.9
Female	HM	9709-0503												3195 40.0		
Female	HM	9709-0504												3190 40.0	4590 48.3	
Female	HM	9709-0506												3505 40.0	4500 48.0	5910 57.1

* Four subjects had more the 9 weights used in growth rate calculation. A complete listing appears on the last page.

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Listing of Weights Included in the Statistical Analyses

Gender	Regimen	SUBJECT	Variable	Wgt1	Wgt2	Wgt3	Wgt4	Wgt5	Wgt6	Wgt7	Wgt8	Wgt9	Wgt10	Wgt11	Wgt12	Wgt13	Wgt14	Wgt15	Wgt16	Wgt17	Wgt18	Growth Rate g/day
Male	Control	9712-0301	Weight (g)	1245	1221	1245	1291	1294	1330	1369	1402	1433	1448	1465								
			Age (weeks pca)	31.6	31.7	31.9	32.0	32.1	32.3	32.4	32.6	32.7	32.9	33.0								26.1
Male	DHA	9707-0307	Weight (g)	1649	1675	1699	1732	1778	1811	1858	1882	1938	1994	2030	2075							
			Age (weeks pca)	32.4	32.6	32.7	32.9	33.0	33.1	33.3	33.4	33.6	33.7	33.9	34.0							39.6
Female	Control	9698-0003	Weight (g)	1020	1050	1070	1080	1080	1060	1080	1070											
			Age (weeks pca)	31.1	31.3	31.4	31.6	31.7	31.9	32.0	32.1											5.6
Female	DHA+ARA	9705-0005	Weight (g)	1075	1120	1185	1280	1310	1310	1265	1350	1380	1440	1450	1510	1515	1565	1585	1640	1680	1670	
			Age (weeks pca)	31.1	31.4	31.7	32.1	32.4	32.7	33.0	33.3	33.4	33.7	33.9	34.0	34.1	34.3	34.4	34.6	34.7	34.9	22.1